

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION THIS DOCUMENT RELATES TO ALL WAVE 1 INVOLVING PROLIFT	Master File No. 2:12-MD-02327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
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RULE 26 EXPERT REPORT OF JERRY G. BLAIVAS

The following report is provided pursuant to Rule 26 of the Federal Rules of Civil Procedure. My opinions are as follows:

I. QUALIFICATIONS

I am a board certified urologist in the state of New York. I attended Tufts College for my bachelor's degree in 1964 and Tufts University School of Medicine for my medical doctorate in 1968. I completed a urology residency in 1976 after completing a general surgery internship followed by a two year general surgery residency. I have been teaching medicine since 1976 at Tufts University School of Medicine, Columbia University, Cornell University and most recently, SUNY Downstate Medical School. Throughout my academic career, I remained a practicing surgeon in a number of hospitals in Massachusetts and New York, and am currently an attending surgeon at The New York Presbyterian Hospital and Lenox Hill Hospital.

I have been a pioneer in the field of female urology, specifically relating to the surgical treatment of female stress urinary incontinence and pelvic organ prolapse. In 1999, I was the recipient of the Lifetime Achievement Award by the Society of Urodynamics and Female Urology (SUFU). This honor was bestowed on me in recognition of my efforts and expertise in the field of urinary incontinence and pelvic organ prolapse. I was the second recipient of the Victor A. Politano Award in 2009. The American Urological Association presents the Victor A. Politano Award annually to an individual in appreciation of their outstanding achievements in the field of urinary incontinence and for enhancing the treatment of incontinent patients." In 2013 I was honored by the Society of Urodynamics and Female Urology as being one of the four "founding fathers" of the new sub-specialty of Female Pelvic Medicine and Reconstructive Surgery. This honor was bestowed on me in recognition of my efforts and expertise in lower urinary tract disorders like incontinence, overactive bladder and pelvic organ prolapse in women. Although I was trained as a urologist, in the mid-1980s, I developed a two team approach to the surgical management of women with incontinence, combining the expertise of the gynecologist expert at

vaginal hysterectomy and prolapse repairs with a urologist, myself, expert at incontinence operations. My goal was for each surgeon, the urologist and the gynecologist to acquire the expertise of the other, so that in the end, only one surgeon would be necessary to perform these complex surgeries. I had already spent some time working with Ted Morgan, a pioneering prolapse and incontinence gynecologic surgeon in Toronto. In New York, at the Presbyterian Hospital, I operated weekly with both Leon Tanzer and Terry Brody, both world renowned gynecologic surgeons. Throughout this period of time, I also collaborated with a number of world renown gynecologic surgeons including David Nichols and George Mitchell.

In the early 1990's, I met with the leaders of the American College of Obstetrics and Gynecology and proposed the formation of a new specialty - urogynecology - combining the expertise of urologists and gynecologists. This was the forme fruste of the sub-specialty of female pelvic medicine and reconstructive surgery. In the mid 1990's, I inaugurated the first ever symposium designed to bring together the expertise of gynecologists and urologists under the auspices of the American Urologic Association. The symposium was named Female Urology and Urogynecology-a Meeting of the Minds. In approximately 1998, Laurie Romanzi, a gynecologist, completed a fellowship under my direction and became the first surgeon that I know of to be trained in both urology and gynecology. In 2002, I began my long collaboration with Mickey Karram who became co-director of the symposium with me.

I have personally managed hundreds of patients with mesh sling and prolapse complications, many resulting from Prolift devices and surgically removed these devices when warranted by complications.

Although I was trained as a urologist, in the mid-1980s, I developed a two-team approach for the surgical management of women with incontinence and pelvic floor problems, combining the expertise of a gynecologist who is an expert in vaginal hysterectomy with a urologist who is an expert in incontinence operations. My goal was for each surgeon, the urologist and the gynecologist, to acquire the expertise of the other, so that in the end, only one surgeon would be necessary to perform these complex surgeries. I had already spent time working with Dr. Ted Morgan, a pioneering prolapse and incontinence gynecologic surgeon in Toronto. In New York, at the Presbyterian Hospital, I operated weekly with both Dr. Leon Tanzer and Dr. Terry Brody, world renowned gynecologic surgeons. Throughout this period of time, I also collaborated with other world renown gynecologic surgeons including David Nichols, Bob Zacharin, and George Mitchell. In the 1990's I inaugurated the first ever symposium designed to bring together the expertise of gynecologists and urologists under the auspices of the American Urologic Association. The symposium was entitled "Female Urology and Urogynecology – A Meeting of the Minds." In 2004, I began my long collaboration with Mickey Karram who became co-director of the symposium. In 2013, I was honored by Society for Urodynamics and Female Urology as one of the four founding "fathers" of the newly recognized sub-specialty Female Pelvic Medicine and Reconstructive Surgery.

I have significant experience with pelvic repair surgery of all types. I have performed thousands of pelvic surgeries for both incontinence and/or prolapse. I have lectured nationally and internationally on these topics. I have personally managed patients with complications resulting from Prolift devices and surgically removed these devices when complications warrant.

II. SUMMARY OF OPINIONS

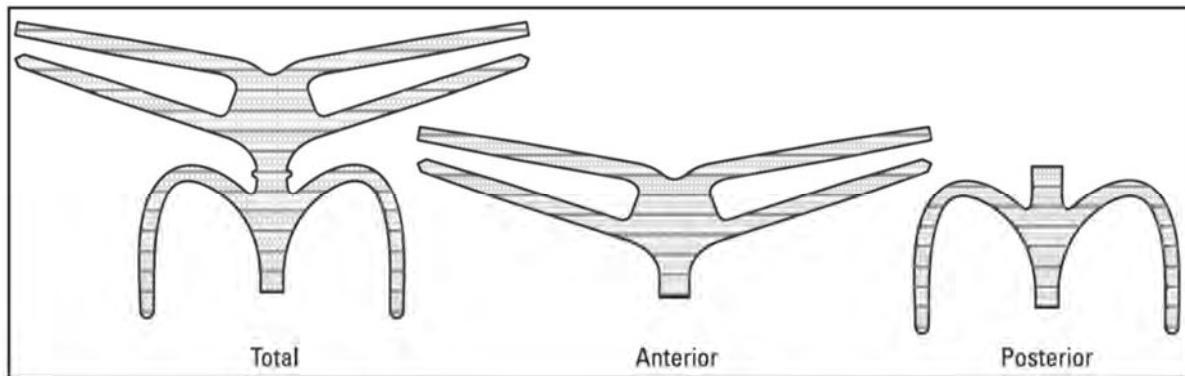
1. Transvaginal polypropylene mesh kits, like Prolift, used to treat Pelvic Organ Prolapse, cause serious and life-style altering complications including, but not limited to, chronic pelvic pain, dyspareunia, infections, nerve injuries, sexual impairment, bowel and bladder dysfunction, fistulas, and vaginal and visceral erosion. These complications often require reoperation and are sometimes permanent.
2. Inherent properties of polypropylene mesh make it a hazardous material to use for vaginal prolapse repairs. These include chronic inflammation and foreign body reaction, shrinkage/contraction, deformation, bacterial colonization, stiffening, fibrosis and scar plate formation, nerve entrapment, degradation, production of unknown and potentially toxic chemicals, and possible carcinogenesis. The mesh arms of the Prolift devices are placed blindly with trocars into spaces that are densely innervated and vascularized. This placement poses a significant risk for complications including, but not limited to, dyspareunia, pain, vaginal scarring and deformation, and shrinkage/contraction.
3. Removal of the Prolift device is extremely difficult, if not impossible with a high likelihood of injuring other structures, particularly the bladder and rectum and failing to alleviate symptoms, especially those related to pain and dyspareunia. In most instances, remnants of mesh remain after removal attempts.
4. Because of risks of removal surgery and unknown best practices, surgeons may elect to do an incomplete operation, subjecting the patient to poor results or further surgery.
5. These serious complications may occur even in experienced hands and when proper surgical technique is used.
6. Prolift procedures are not “minimally invasive.”
7. The incidence of these complications is unacceptably high.
8. Appropriate and unbiased clinical testing, if performed, would have shown the problems and complications associated with polypropylene mesh kits.
9. Ethicon should have had a high level of suspicion as to the performance of the Prolift devices based on predicate products.
10. Ethicon’s warnings were inaccurate and misleading and did not provide physicians with the information needed to make responsible decisions and obtain informed consent from patients.
11. The Prolift devices are defective from a clinical standpoint. Flaws in the design include, but are not limited to, the choice of material, the blind trocar-based insertion method, the

presence of arms with sharp edges implanted in high-risk areas, high complication rates, and the inability to remove.

12. Ethicon marketed these products to inadequately trained physicians.
13. There are alternative procedures that are safer and equally or more effective.
14. The risks of the Prolift devices outweigh any benefits.
15. Through the Pelvic Health Coalition, Ethicon joined forces with other mesh manufacturers to influence reimbursement of mesh procedures through false and misleading information and in complete disregard to patient safety.

III. DESCRIPTION OF THE DEVICE/PROCEDURE

The Prolift Pelvic Floor Repair Systems were marketed to physicians beginning in 2005 (even though FDA clearance was not obtained until three years later). These “kits” (anterior, posterior, and total) all contained a pre-cut piece of polypropylene mesh specific to the compartment (Gynemesh PS), the trocars/instruments necessary to insert the mesh devices, a Prolift Surgical Guide, and Instructions for Use. Prolift Anterior was designed to treat a cystocele; Prolift Posterior was designed to treat rectocele; and Prolift Total was designed to treat cystocele, rectocele, and vaginal vault prolapse. Gynemesh PS (cleared in 2002) is the same mesh as Prolene PS mesh, which was cleared by Ethicon in 2000 for the treatment of abdominal wall hernias. Ethicon marketed Gynemesh to urologists, gynecologists, and urogynecologists as “uniquely” designed to treat pelvic organ prolapse, even though there were no studies to support this claim.¹



Whereas Prolene PS was designed for hernia repairs, Gynemesh PS and Prolift meshes were specifically designed to be used for “vaginal tissue reinforcement and long-lasting

¹ See e.g., ETH.MESH.02280771; ETH.MESH.01156032; ETH-07152; ETH-00252: (“Technologically Advanced by Design – Driven by Innovation”; ETH-00253: “Unique Permanent Material for Durable Solutions”; ETH-00382 (“innovative”; ETH-00384 “Evolution in design for pelvic floor restoration”).

stabilization of fascial structures of the pelvic floor in vaginal wall prolapse.”² According to internal documents, in as early as 1998, Ethicon knew that Gynemesh was not an appropriate mesh for use in the surgical treatment of pelvic organ prolapse, but persisted in launching Gynemesh for prolapse surgery for these reasons: “to raise awareness of the possibility of using a mesh for prolapse repair; to gain entry into this growing market before competitors; to spend time seeking out key surgeons as product champions and to allow time to carry out further market research into what the ideal product for this indication might be.”³

The Instructions for Use state, “Gynemesh PS elicits a minimum to slight inflammatory reaction, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The mesh remains soft and pliable, and normal wound healing is not noticeably impaired. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.”⁴ There is ample evidence in the scientific literature, Ethicon corporate documents, and Ethicon employee depositions that this statement is inaccurate – even at the time of the introduction of Prolift. Despite literature to the contrary and confirmatory internal corporate knowledge, Ethicon never changed the IFU to reflect: 1) the inflammatory response is persistent and not transient; 2) the mesh creates dense scar tissue not a “thin layer of tissue”; and 3) the material is, in fact, subject to degradation.⁵

The pre-cut mesh pieces and the instruments contained in the “kit” dictate the procedure. The Prolift operation is a radical departure from any other traditional prolapse repair.⁶ It is a complex and difficult procedure to perform with little margin of error when it comes to proper placement. Even Altman⁷ and colleagues conclude: “The longer duration of surgery, more frequent use of intraoperative cystoscopy, and greater frequency of bladder perforations and pelvic hemorrhage associated with mesh repair in our study are consistent with the more invasive nature of this procedure as compared with colporrhaphy.” It is “not minimally invasive” as claimed by Ethicon in its promotional materials.⁸

² ETH.MESH.01154032.

³ ETH. MESH.12009028.

⁴ See e.g., ETH.MESH.02341522; ETH.MESH.00015690; ETH.MESH.02341454.

⁵ ETH.MESH.02341522; ETH.MESH.02341454; ETH.MESH.02001398.

⁶ See e.g., ETH.MESH.02282833 (“The TVM represents a MAJOR mind shift on several key aspects of prolapse surgery that may require a greater shift in thinking: ... Passage THROUGH the sacrospinal ligaments: -- All of these are new concepts and will require good back up during the education process to explain why they are essential to good results.”).

⁷ Altman, et al., Anterior Colporrhaphy versus Transvaginal Mesh for Pelvic-Organ Prolapse. N Engl J Med 2011; 364:1826-36.

⁸ See e.g., ETH.MESH.03905968.

According to the surgical instructions for use provided by Ethicon, “It is preferred to leave Halban’s fascia (pubocervical fascia) on the vaginal wall.”⁹ This technique places the mesh directly in contact with the bladder wall. It is well documented that the polypropylene mesh incites an inflammatory reaction and, ultimately tissue ingrowth. This technique, recommended by Ethicon, unnecessarily places the bladder at risk for erosion, fistula, scar formation and the development of de novo overactive bladder. In addition, it enhances the likelihood of the mesh becoming incorporated into the bladder wall.

IV. DISCUSSION OF OPINIONS

Transvaginally-placed mesh kits, such as the Prolift devices, cause serious and life-style altering complications including chronic pelvic pain, dyspareunia, nerve injuries, fistulas, urethral obstruction, bladder stones, and vaginal, urethral, and bladder erosion. This opinion is based not only on my own firsthand experience with hundreds of such complications, but also the knowledge gained by speaking to my peers. I have personally operated on over 100 patients with severe synthetic mesh complications, but I have taken care of hundreds more who either did not elect further surgery with me or who simply gave up and were seeking relief from pain management experts.¹⁰ Many patients require multiple operations.

A permanent implantable device, such as the Prolift devices, should not have been designed for placement in a surgically contaminated field, at least without proper animal and clinical studies to document safety and without a clear warning about the possibility of short and long term complications.¹¹ Bacteria attaches to mesh during the insertion process.¹² Infection, even if subclinical, can result in chronic inflammation, scarring, pain, and functional bladder and bowel problems.

⁹ ETH.MESH.00419571.

¹⁰ Deng, et al., (2007). Presentation and management of major complications of midurethral slings: Are complications under-reported? *Neurourol Urodyn*, 26(1), 46-52.; Reynolds, et al. (2012). Obturator foramen dissection for excision of symptomatic transobturator mesh. *J Urol*, 187(5), 1680-1684.; Blaivas, J. G. & Chaikin, D. C. (2011). Pubovaginal fascial sling for the treatment of all types of stress urinary incontinence: surgical technique and longterm outcome. *Urol Clin North Am*, 38(1), 7-15.; Ogah, J., et al. (2011). Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women: a short version Cochrane review. *Neurourol Urodyn*, 30(3), 284-291.; Kobashi, K. C., et al., (1999). Erosion of woven polyester pubovaginal sling. *J Urol*, 162(6), 2070-2072.; FDA Executive Summary.” Web; Anger, J. T., et al. (2007). Complications of sling surgery among female Medicare beneficiaries. *Obstet Gynecol*, 109(3), 707-714.

¹¹ Culligan, P., et al. (2003). Bacterial colony counts during vaginal surgery. *Infect Dis Obstet Gynecol*, 11(3), 161-165.; Vollebregt, A., et al. (2009). Bacterial colonisation of collagen-coated polypropylene vaginal mesh: are additional intraoperative sterility procedures useful? *Int Urogynecol J Pelvic Floor Dysfunct*, 20(11), 1345-1351.; Choi, J. J., et al. (2012). Use of mesh during ventral hernia repair in clean contaminated and contaminated cases: outcomes of 33,832 cases. *Ann Surg*, 255(1), 176-180.

¹² See e.g., Vollebregt, et al. (2009); Mahmoud, W. M., et al. (1993). Migration of bacteria along synthetic polymeric fibers. *Journal Of Biomaterials Science. Polymer Edition*, 4(6), 567-578; Klinge, U., Klosterhalfen, B., et al. (1998). Shrinking of polypropylene mesh in vivo: an experimental study in dogs. *Eur J Surg*, 164(12), 965-969.

The arms of the Prolift devices create specific problems. These are inserted blindly with trocars through densely vascularized and innervated areas. The edges are sharp and can saw through delicate tissues.¹³ There is no such thing as a “tension-free” insertion. These arms undergo stress and stretching at the time of insertion and afterwards as the body reacts to the foreign body. This results in curling, roping, and coiling.¹⁴ Tissue injury can occur at the time of placement or subsequently as the mesh deforms and contracts.

Even though the surgeon may feel that the mesh implant is lying flat at the time of implantation, the mesh is prone to shrink unpredictably and asymmetrically, influenced by individual response, bacterial contamination, anatomical location, and time.¹⁵ Mesh deforms *in vivo*. Retraction, shrinkage, banding, bunching, and folding lead to pain and contracture.

There is evidence that polypropylene mesh degrades *in vivo*¹⁶ and that degradation results in stiffening of the mesh, perpetuation of the inflammatory response, creation of a nidus for bacteria and other organisms, and the production of unknown and potentially toxic and/or carcinogenic chemicals. The breakdown of mesh is expected to result in the presence of small molecular complexes and chemical products of degradation, as is the case for any polymerized hydrocarbon. Accumulations of polypropylene degradation products are expected to be confined within the scar capsule and have more local, rather than systemic, effects on the body, owing to their fibrous encapsulation; however, no published studies currently address this point. The degradation products might act as an additional stimulus for the chronic inflammatory response.

¹³ ETH.MESH.03904451.

¹⁴ ETH.MESH.00034875 (“Another point is that the tight-knit arms would result in a rope effect. Knowing that the tissue needs to grow through the arms as-well, this will be problematic in the patient. To be fair, it is an issue for everyone because if you ‘yank’ Gynemesh arms, they will also lose their porosity. The effect of roping is increased inflammatory response, increased risk of infection and denser scar plate (not much fun for the patient) . . .”); ETH-80645; Kirkemo dep. (4-18), at p.135-138, p.150; Hinoul dep. (4-6), p.506-507.

¹⁵ See e.g., Mesh shrinkage: How to assess, how to prevent, how to manage? PowerPoint (“Mesh Shrinkage . . . Is real! . . . May result in unpredictable way in severe complications including dyspareunia, pain and recurrence.”); Mamy, L., et al. (2011). Correlation between shrinkage and infection of implanted synthetic meshes using an animal model of mesh infection. *Int Urogynecol J*, 22(1), 47-52. ; Letouzey, V., et al. (2012). Is polypropylene mesh coated with antibiotics efficient to prevent mesh infection and contraction in an animal infectious model? [Abstract]. 37th Annual Meeting of the International Urogynecological Association, 193; Jacquetin, B., & Cosson, M. (2009). Complications of vaginal mesh: our experience. *Int Urogynecol J Pelvic Floor Dysfunct*, 20(8), 893-896.; Feiner, B., & Maher, C. (2010). Vaginal mesh contraction: definition, clinical presentation, and management. *Obstet Gynecol*, 115(2 Pt 1), 325-330.; Tunn, R., et al. (2007). Sonomorphological evaluation of polypropylene mesh implants after vaginal mesh repair in women with cystocele or rectocele. *Ultrasound Obstet Gynecol*, 29(4), 449-452.

¹⁶ Iakovlev VV, et al. *Degradation of polypropylene in vivo: A microscopic analysis of meshes explanted from patients*. *J Biomed Mater Res B Appl Biomater*. 2015 Aug 28. doi: 10.1002/jbm.b.33502. [Epub ahead of print].; Jongebloed, W. L. & Worst, J. F. (1986). Degradation of polypropylene in the human eye: a SEM-study. *Documenta Ophthalmologica. Advances In Ophthalmology*, 64(1), 143-152.; Coda, A., et al. (2003). Structural alterations of prosthetic meshes in humans. *Hernia: The Journal Of Hernias And Abdominal Wall Surgery*, 7(1), 29-34.; Costello, C. R., et al. (2007). Materials characterization of explanted polypropylene hernia meshes. *Journal of Biomedical Materials Research Part B: Applied Biomaterials*, 83B(1), 44-49.; Clavé, A., et al. (2010). Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants. *Int Urogynecol J*, 21(3), 261-270.; Sternschuss, G. (2012). Post-Implantation Alterations of Polypropylene in the Human. *J Urol*. 188 (7), 27-32.

Accumulation and toxicity of these degradation products might cause tissue damage and contribute to the continuous remodeling around the mesh filaments and extension of fibrosis.¹⁷ I recently published a review article in *Nature*.¹⁸ Although this article dealt primarily with slings, the discussion of the material properties of polypropylene mesh when used in the vagina and the body's responses are the same as those seen with prolapse devices. These properties are well reported elsewhere and, based on my review of corporate documents, known to Ethicon.¹⁹

Ethicon marketed Prolift as a one-size-fits-all technique for prolapse repair that is reproducible.²⁰ However, the anatomy of prolapse and the relationship between surface landmarks and vital structures varies from individual to individual and even in the same individual, making accurate and safe placement of trocars unpredictable..” For example, positioning of the patient in various degrees of dorsal lithotomy position can impact the locations of nerves and blood vessels. The size of the obturator foramen and the bony pelvis can vary.²¹ The Prolift devices pass dangerously close to vital structures.²² Although bleeding can often be controlled, nerve injuries can have disastrous consequences.

Claims that make the procedure sound as if it is safer and easier to perform than it actually is are misleading. The goal was sound – a simple, safe, efficacious, outpatient procedure that required minimal surgical skills and could be mastered by surgeons with little training.²³ But the

¹⁷ Junge, K. et al. Persistent extracellular matrix remodelling at the interface to polymers used for hernia repair. *Eur. Surg. Res.* 35, 497–504 (2003).

¹⁸ Blaivas, J. G. et al., Safety considerations for synthetic sling surgery. *Nat Rev Urol.* 2015 Sep;12(9):481-509. (Epub 2015 Aug 18).

¹⁹ See e.g., ETH.MESH.02589032; Mesh shrinkage: How to assess, how to prevent, how to manage? PowerPoint.

²⁰ See e.g., ETH-03430 (“Gynecare’s challenge is to enter the market with a product *and* technique that will allow gynecologists, urogynecologists, and urologists to perform a quick, efficient and reproducible procedures for the treatment of these pathologies.”); ETH.MESH.00419571, at p. 2 (“The objective of the Prolift procedure is to achieve a complete anatomic repair of pelvic floor defects in a standardized way.”).

²¹ Whiteside JL, Walters MD. Anatomy of the obturator region: relations to a trans-obturator sling. *Urogynecol J Pelvic Floor Dysfunct.* 2004 Jul-Aug;15(4):223-6.; LitWiller, J., et al. Effect of Lithotomy Positions on Strain of the Obturator and Lateral Femoral Cutaneous Nerves. *Clinical Anatomy* 17:45-49 (2004).

²² Whiteside, JL (2004); Atassi, Z., et al. Haemorrhage and nerve damage as complications of TTVT-O procedure: case report and literature review. *Arch Gynecol Obstet* (2008) 277:161–164.; Marqués Queimadelos A, et al. (2004) Cabestrillo suburetral transobturator en el tratamiento de la incontinencia urinaria de esfuerzo femenina. *Rev Med Univ Navarra* 48:62–69.; Hazewinkel, M., et al. Persistent groin pain following a trans-obturator sling procedure for stress urinary incontinence: a diagnostic and therapeutic challenge. *Int Urogynecol J* (2009) 20:363–365.; Hinoul, P., et al. Anatomical variability in the trajectory of the inside-out transobturator vaginal tape technique (TTV-T-O). *Int Urogynecol J* (2007) 18:1201–1206.; Spinoza JP, et al.. Transobturator surgery for female urinary continence: a comparative anatomic study of outside-in vs inside-out techniques. *Prog Urol* 15(4):700-6, 2005. *BJU International* 2007 Journal Compilation, 100, 1097-1102.

²³ ETH-60149 (“One of our biggest challenges moving forward will be our ability to clearly communicate with our physicians how to use Gynemesh tension free in POP procedures. This will also help to ensure a healthy pipeline of targets for Prolift moving forward. This information should be helpful in shorten [sic] the learning curve with your physicians that are just starting to use mesh. We need to prepare our future Prolift users, today.”).

truth is very different. The fact is, it is not so easy to learn these techniques and the ergonomics of the trocars are such that it is easy to misguide them and end up in the wrong place. Because the company so trivialized the learning curve and potential complications, many surgeons with inadequate skill and experience perform these surgeries. In addition, there is ample evidence in the literature that it is very common for the trocars to inadvertently puncture vital structures during trocar passage.²⁴

Due to tissue ingrowth, it is very difficult and often impossible to remove the entire mesh and, in most instances, there are remnants of mesh that remain after explant surgery. This is well known.²⁵ The arms of the Prolift devices are implanted in spaces that are not easily accessed and foreign to most urologists and gynecologists. The sheer size and configuration of the Prolift meshes alone make complete removal virtually impossible. Further, these explant surgeries are risky and have their own set of complications. It is impossible to remove the device without also excising healthy tissue. Further, the mesh that remains behind can form the nidus for infections, stones, more erosion, scar formation or extrusion and pain. There are neither published guidelines nor good studies of the outcomes after mesh removal. Consequently explant surgery is mostly empiric and many surgeons opt to do an incomplete operation, subjecting the patient to poor results or further surgery.²⁶ On the other hand, overzealous surgeons who attempt to remove all the mesh may cause even more problems. In brief, when performing explant surgery, most surgeons simply do not know what is best.

The management of mesh complications is fraught with complexity and results in a high rate of persistent symptoms.²⁷ Appropriate and unbiased clinical testing, if performed, would have

²⁴ See e.g., Bhoyrul S, et al. Trocar injuries in laparoscopic surgery. Journal of the American College of Surgeons. 2001;192(6):677-83.; Shindel AW, Klutke CG. Urethral slings placed by the transobturator approach: evolution in the technique and review of the literature. Current Urology Reports. 2005;6(5):385-92.; Takeyama M et al. Nerve preservation in tension-free vaginal mesh procedures for pelvic organ prolapse: a cadaveric study using fresh and fixed cadavers. Int Urogynecol J 2008 Apr; 19(4): 559-566. Epub 2007 Oct 10.; Chen CCG et al. Anatomic relationships of the tension-free vaginal mesh trocars. Am J Obstet Gynecol 2007; 197: 666.e1-666.e6.; Roundtable: Using mesh to repair prolapse: Averting, managing complications. Karram MM, moderator. OBG Management 2009; 21 (2): 21-28.; see e.g., ETH.MESH.00857821; ETH-02601.

²⁵ Reynolds, W. S., et al. (2012). Obturator foramen dissection for excision of symptomatic transobturator mesh. J Urol, 187(5), 1680-1684.

²⁶ Barber M., Surgical Techniques for Removing Problematic Mesh, Clinical Obstetrics and Gynecology, Volume 56, Number 2, 289–302

²⁷ See e.g., Barski D and Deng DY. Management of mesh complications after SUI and POP repair: Review and analysis of the current literature. Biomed Res Int. 2015;2015:831285. [Epub 2015 Apr 20].; Lee D, et al. Meshology: a fast-growing field involving mesh and/or tape removal procedures and their outcomes. Expert Rev Med Devices. 2015 Mar;12(2):201-16; Dunn, et al., Changed Women: The Long-Term Impact of Vaginal Mesh Complications. Female Pelvic Med Reconstr Surg 2014;20: 131Y136.; Unger, C., et al. Outcomes following treatment for pelvic floor mesh complications. Int Urogynecol J. 2014 Jun;25(6):745-9.; Skala, CE, et al. Mesh complications following prolapse surgery: management and outcome. Eur. J Obstet. Gynecol. 159 (2011) 453-456.; Nguyen, JN, et al. Perioperative Complications and Reoperations after Incontinence and Prolapse Surgeries Using Prosthetic Implants. Obstet Gynecol 2012;119:539–46; Huffaker, et al. A serious complication following placement of posterior Prolift, Int Urogynecol J (2009) 20:1383–1385; Brubaker and Shull, A perfect storm, In t Urogynecol J (2012) 23:3-4;

shown the problems and complications associated with armed pelvic organ prolapse kits, like Ethicon's Prolift. Because of the known complications, many occurring years after the original surgery,²⁸ it behooved the company to conduct long-term clinical trials or at least monitor complications through a registry. Had they done this Ethicon undoubtedly would have uncovered the complications.

The most debilitating and challenging complication to treat is chronic pain, especially as it is seen with transvaginally-placed mesh for prolapse.²⁹ This pain can be located in the abdomen, pelvis, vagina, buttocks, perineum, groin, or leg. It can be acute (occurring immediately after surgery) or chronic with an insidious onset. It is often refractory to traditional treatments. It can be related to erosion; scarring; mesh deformation; entrapment or compression of large nerves with classic or atypical nerve distribution; entrapment of smaller nerve branches with diffuse distribution; muscular inflammation, scarring, trauma, and hypertonicity; or visceral pain syndromes. It may be associated with other sensory changes such as numbness and tingling. It may continue, or even worsen, after mesh excision or revision.³⁰ New treatment modalities for pelvic pain have been developed as a response to this pain management challenge, rarely used in urology or gynecology until the appearance of mesh-related pain. These include trigger point injections, nerve blocks, Botox injection, physical therapy, treatment with medications for chronic, neuropathic pain, and referral to contract-based pain management programs.³¹

The complications discussed in this report and in the medical literature are a result of the defects in the device itself. Complications may occur even in experienced hands and when proper surgical technique is used.³² Ethicon's marketing materials suggest that these complications occur mostly because of faulty surgical technique performed by inexperienced or poorly trained surgeons, perhaps by "over-tensioning" or misplacement. However, I have firsthand knowledge

Hurtado, E. and Appell, R. Management of complications arising from transvaginal mesh kit procedures: a tertiary referral center's experience. *Int Urogynecol J* (2009) 20:11–17.

²⁸ See e.g., Hansen, B., et al. Long-Term Follow-up of Treatment for Synthetic Mesh Complications. *Female Pelvic Med Reconstr Surg*. 2014 May-Jun;20(3):126-30.

²⁹ Rogo-Gupta, L. and Raz, S. Pain Complications of Mesh Surgery. H.B. Goldman (ed.), *Complications of Female Incontinence and Pelvic Reconstructive Surgery*, 87 *Current Clinical Urology*; Bako, A. and Dhar, R. Review of synthetic mesh-related complications in pelvic floor reconstructive surgery. *Int Urogynecol J* (2009) 20:103–111; Lin, LL, et al. Dyspareunia and chronic pelvic pain after polypropylene mesh augmentation for transvaginal repair of anterior vaginal wall prolapse. *Int Urogynecol J* (2007) 18:675–678.

³⁰ Crosby, EC, et al. Symptom Resolution After Operative Management of Complications From Transvaginal Mesh. *Obstet Gynecol* 2014;123:134–9.; Lee, D., et al. Transvaginal Mesh Kits—How “Serious” Are the Complications and Are They Reversible? *UROLOGY* 81: 43e49, 2013.; Margulies, RU, et al. Complications requiring reoperation following vaginal mesh kit procedures for prolapse. *Am J Obstet Gynecol* 2008;199:678.e1-678.e4.; Unger, C., et al. Outcomes following treatment for pelvic floor mesh complications. *Int Urogynecol J*. 2014 Jun;25(6):745-9.

³¹ See e.g., Gyang, AN, et al. Managing chronic pelvic pain following reconstructive pelvic surgery with transvaginal mesh. *Int Urogynecol J* (2014) 25:313–318.

³² See e.g., Iglesia CB, et al. Vaginal mesh for prolapse: a randomized controlled trial [reply]. *Obstet Gynecol* 2010; 116: 1457 (“If expert surgeons from multiple institutions cannot get the outcomes of a few individuals, perhaps there is something wrong with the procedure”).

that is not the case. In the course of my practice, I have seen mesh complications from many world renowned experts and, from discussions with my colleagues, I know of many others. The peer-reviewed literature also supports this concept.³³

Mesh complications are significantly under-reported.³⁴ Additionally, most patients who experience complications do not return to their original surgeons, contributing to a misperception among individual physicians that their outcomes are better than they, in fact, are.³⁵

I have reviewed the Instructions for Use for the Prolift devices. Ethicon did not warn doctors and patients about the chronic and lifestyle altering nature of the complications associated with its products which included chronic and debilitating pain, dyspareunia, sexual impairment, nerve injuries, vaginal scarring, bladder dysfunction, new onset stress urinary incontinence, severe bladder and bowel dysfunction, the need for multiple corrective surgeries, and others.³⁶ Because the company so trivialized the learning curve and potential complications, many surgeons with inadequate skill and experience perform these surgeries. Ethicon did not warn doctors and patients about the difficulty removing their Prolift products and the poor or less than optimal results when excision or revision becomes warranted due to complications. Ethicon did not attempt to establish best practices for management of complications.³⁷

I have reviewed the Material Safety Data Sheet for the polypropylene used in the Prolift medical devices.³⁸ This document, under INCOMPATIBILITY, states that the following materials are incompatible with this product: "Strong oxidizers such as chlorine, peroxides, chromates, nitric acid, perchlorates, concentrated oxygen, sodium hypochlorite, calcium hypochlorite and permanganates. Chlorine; Nitric acid." And yet, many of these chemicals are routinely found in human tissue. The document also states under COMPONENT TOXICITY: "Polypropylene has

³³ Jacquetin, B, et al. Total transvaginal mesh (TVM) technique for treatment of pelvic organ prolapse: a 3-year prospective follow-up study. *Int Urogynecol J* (2010) 21:1455–1462.

³⁴ See e.g., Deng, D. Y., et al. (2007). Presentation and management of major complications of midurethral slings: Are complications under-reported? *J Neurourol Urodyn*. 2007;26(1):46-52.; Anger, J. T., et al. (2007). Complications of sling surgery among female Medicare beneficiaries. *Obstet Gynecol*, 109(3), 707-714.

³⁵ Blandon, R., et al. (2009). Complications from vaginally placed mesh in pelvic reconstructive surgery. *Int Urogynecol J* 20, 523-531.; Rostamnia, G., Shobeiri, A., et al. Referral pattern for vaginal mesh and graft complications to the University of Oklahoma Pelvic and Bladder Health Clinic. *J Okla State Med Assoc*. 2012; 105(9):356-8.; Ostergard, D. Lessons from the past: directions for the future. *Int Urogynecol J* (2007) 18:591-598.

³⁶ ETH.MESH.02341522; ETH.MESH.02341454; ETH.MESH.02001398; see e.g., ETH-03558; ETH.MESH.00267981 at 00237992; ETH-08343 (erosion and abscess formation); ETH-10127; ETH-08926 (pain); ETH-08894; ETH-08776; ETH-00639; ETH-09541 (erosion, fistula, pain); see also, ETH.MESH.00164023. See e.g., Zhang, L, et al. Postoperative voiding difficulty and mesh-related complications after Total Prolift System surgical repair for pelvic organ prolapse and predisposing factors. *Menopause*. 2015 Aug;22(8):885-92.

³⁷ Blaivas, J. G., et al. (2013). Salvage Surgery after Failed Treatment of Synthetic Mesh Sling Complications. *J Urol*. 2013 Oct;190(4):1281-6.; Unger, C., Abbot, S., Evans, J., Jallad, K., Mishra, K., Karram, M., Iglesia, C., Rardin, C., Barber, M. Outcomes following treatment for pelvic floor mesh complications. *Int Urogynecol J*. 2014 Jun;25(6):745-9.

³⁸ Sunoco 2004 MSDS; Sunoco 2006 MSDS; Sunoco 2005 MSDS.

been tested in laboratory rats by subcutaneous implantation of discs or powder. Local sarcomas were induced at the site of implantation.” Ethicon IFUs do not include the toxic and carcinogenic warnings contained in the MSDSs. Ethicon marketing materials for doctors and patients do not include the toxic and carcinogenic warnings contained in the MSDSs.³⁹

I have reviewed the literature regarding the safety and efficacy of Prolift, as well as the literature regarding mesh kits for the repair of prolapse generally. In my opinion, the medical literature does not support the conclusion that the Prolift devices are safe and there are a number of studies that call into question its efficacy. Summaries of some of the more important studies are included in this report.

In 2010, Jacquetin⁴⁰ reported on the 3-year results of a study French TVM. At 1-year follow-up, recurrent prolapse was reported in 17.4% of patients; at 3-years, 20% had failed. Over the three year period, 33.3% of patients had reoperations for recurrence, complications (exposure, vesicovaginal fistula, hematoma), and stress urinary incontinence. Moderate or severe vaginal stiffness (loss of elasticity) could be detected by digital examination in 11 (12.6%) patients after 1 year. Of the 61 patients who were sexually active at baseline, only 36 (59%) remained so at 3 year.

Velemir⁴¹ also reported on the French TVM study (2010), looking at mesh retraction. Patients with no, moderate (<50%) or severe ($\geq 50\%$) mesh retraction were compared. Mesh retraction, also known as mesh shrinkage or contraction, was defined, in this study, as a reduction of the surface area of the original implanted mesh. Velemir found that anterior mesh retraction was moderate in 80% and severe in 9.3% in the patients studied. Posterior mesh retraction was moderate in 48.4% and severe in 9.7% of patients. With both anterior and posterior Prolift mesh implants, mesh retraction was strongly associated with increased mesh thickness and higher frequency of recurrent prolapse. The authors also concluded that “over time it appeared that mesh retraction was probably a contributing factor to recurrence, postoperative pain and dyspareunia.”

The U.S. TVM study, reported in 2011 by Miller,⁴² provided 5-year results. The overall failure rate was 33.3% at 5 years. The authors inaccurately used the total study population as the denominator for calculating complications rather than the number of patients who participated in the 5 year evaluation. The true mesh exposure rate was 24% and voiding dysfunction rate 9%. A total of 44% (29 of 66 women) required reoperation, including 13 for stress incontinence, at least 9 for mesh exposure, 5 for recurrent prolapse, and 2 for fistulas. Similar to the French TVM study, nearly one-third of preoperatively sexually active women abandoned sexual activity after the Prolift procedure,

³⁹ ETH.MESH.02341522;ETH.MESH.02341454;ETH.MESH.02001398;ETH.MESH.03905968;ETH.MESH.03905976; ETH.MESH.03905992; ETH.MESH.03906001; ETH.MESH.03906037.

⁴⁰ Jacquetin, B, et al. Total transvaginal mesh (TVM) technique for treatment of pelvic organ prolapse: a 3-year prospective follow-up study. Int Urogynecol J (2010) 21:1455–1462.

⁴¹ Velemir, L., Transvaginal mesh repair of anterior and posterior vaginal wall prolapse: a clinical and ultrasonographic study. Ultrasound Obstet Gynecol 2010; 35: 474–480.

⁴² Miller, D., et al. Prospective Clinical Assessment of the Transvaginal Mesh Technique for Treatment of Pelvic Organ ProlapseV5-Year Results. Female Pelvic Med Reconstr Surg 2011;17: 139-143.

A randomized controlled trial of Prolift vs. traditional anterior colporrhaphy was begun in 2007 and reported in 2010⁴³. The trial was halted early because of an unacceptably high rate of vaginal erosion (15.6%). Sokol⁴⁴ reported 1-year results on the same cohort of patients. At 12 months, both groups had improvement of pelvic organ prolapse, but mesh repairs had higher reoperation rates. The authors concluded: Nonetheless, properly designed clinical trials are necessary to evaluate whether synthetic mesh confers benefit for vaginal prolapse repair. Based on the results of this study and the high exposure rates that have been noted in other studies, it is very likely that the risks outweigh the benefits for the older trocar-based mesh systems, even when fellowship-trained pelvic reconstructive surgeons perform these procedures.

Altman⁴⁵ published the results of a randomized controlled study with Prolift Anterior and anterior colporrhaphy. The mesh repair group, as compared with the anterior colporrhaphy group, had a significantly longer mean duration of surgery, greater mean intraoperative blood loss, more frequent need for intraoperative cystoscopy, and more bladder perforations. The mesh group also had higher rates of new onset stress urinary incontinence. As compared with anterior colporrhaphy, use of a standardized, trocar-guided mesh kit for cystocele repair resulted in higher short-term rates of successful treatment, according to the authors, but also in higher rates of surgical complications and postoperative adverse events.

Withagen published two articles reporting on the same study population, a randomized controlled trial of Prolift anterior vs. traditional non-mesh repair. All patients in the study had recurrent prolapse. At one year,⁴⁶ anatomic outcomes were better in the Prolift group, but subjective improvement occurred in equal proportions in both groups (80% in Prolift and 81% non-mesh). Intraoperative and postoperative complications were more frequent in the Prolift group. In the Prolift group, 16.9% developed mesh exposure. The authors recognized that “the effects of long-term presence of non-absorbable mesh in the vagina is unknown and a reason for concern.” Because the long-term effects and safety of mesh-reinforced repairs are not yet fully known, surgeons may consider these procedures primarily for recurrent vaginal prolapse after counseling patients on the risks and benefits. In the second article (2012),⁴⁷ Withagen reported a much higher frequency of new prolapse in untreated compartments in the Prolift group. At 1 year after surgery, 10 of 59 women (17%) in the non-mesh group versus 29 of 62 women (47%) in the Prolift group were diagnosed with new prolapse stage II or higher in the untreated compartment.

⁴³ Iglesia, C., et al. Vaginal Mesh for Prolapse, A Randomized Controlled Trial. *Obstet Gynecol* 2010;116:293–303.

⁴⁴ Sokol, AI, et al. One-year objective and functional outcomes of a randomized clinical trial of vaginal mesh for prolapse. *Am J Obstet Gynecol* 2012;206:86.e1-9.

⁴⁵ Altman, et al., Anterior Colporrhaphy versus Transvaginal Mesh for Pelvic-Organ Prolapse. *N Engl J Med* 2011; 364:1826-36.

⁴⁶ Withagen, MI, et al. Trocar-Guided Mesh Compared With Conventional Vaginal Repair in Recurrent Prolapse. *Obstet Gynecol* 2011;117:242-50.

⁴⁷ Withagen, MI, Development of de novo prolapse in untreated vaginal compartments after prolapse repair with and without mesh: a secondary analysis of a randomised controlled trial. *BJOG* 2012;119:354–360.

These articles are consistent with my experience. Improved anatomic results are misleading and likely the result of stiffening and loss of compliance in the vaginal wall. Complications are greater in mesh repairs and reoperations higher. New onset stress urinary incontinence and prolapse in a non-mesh compartment occur frequently and are also a result of the non-anatomical correction provided with the Prolift devices.

Mesh complications are also significantly under-reported.⁴⁸ In addition, most patients who experience complications do not return to their original surgeons, contributing to a misperception among individual physicians that their outcomes are better than they, in fact, are.⁴⁹ Even though the medical literature for transvaginally-placed prolapse mesh is flawed for reasons including, but not limited to, industry sponsorship, bias, industry manipulation of data, inappropriate choice of outcome variables, and lack of long-term follow-up, the results are not good.

Regarding **efficacy of mesh kits**, I agree with the conclusions that the FDA made from their own literature review: “The literature review found that while transvaginal POP repair with mesh often restores anatomy, it has not been shown to improve clinical benefit over traditional non-mesh repair.”⁵⁰

- Although there was some early evidence of anatomic improvement with repair using mesh in the anterior compartment, there is little evidence that POP repair surgery with mesh results in any better outcomes in terms of relief of symptoms and QOL measures, which ultimately are the clinically significant indicators for measuring treatment success for this condition.
- There is no evidence that transvaginal apical or posterior wall repair with mesh results in a better anatomic outcome than repair without mesh.
- Most of the recurrences of prolapse following transvaginal surgery, with or without mesh placement, are at a low stage, are asymptomatic, and do not require further intervention.
- To date, no study comparing transvaginal surgery for anterior wall prolapse with surgical mesh placement to surgery without mesh has demonstrated convincingly a clinically

⁴⁸ See e.g., Deng, D. Y., et al. (2007). Presentation and management of major complications of midurethral slings: Are complications under-reported? *Neurourol Urodyn*, 26(1); Anger, J. T., et al. (2007). Complications of sling surgery among female Medicare beneficiaries. *Obstet Gynecol*, 109(3).

⁴⁹ Blandon, R., et al. (2009).Complications from vaginally placed mesh in pelvic reconstructive surgery. *Int Urogynecol J* 20, 523-531.; Parnell, B., Johnson, E., & Zolnoun, D. Genitofemoral and Perineal Neuralgia After Transobturator Midurethral Sling. *Obstet Gynecol* (2012;119) 428–431.; Rostamnia, G., Shobeiri, A., et al. Referral pattern for vaginal mesh and graft complications to the University of Oklahoma Pelvic and Bladder Health Clinic. *J Okla State Med Assoc*. 2012; 105(9):356-8.; Ostergard, D. Lessons from the past: directions for the future. *Int Urogynecol J* (2007) 18:591-598.

⁵⁰ FDA, Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse (July 2011).

significant difference in terms of subjective success, QOL outcomes, and reoperation for prolapse or incontinence.

- Mesh repairs invariably have a higher rate of reoperations when recurrent prolapse and complications are considered.

Although mesh kits were marketed based on perceived high failure rates with native tissue repairs, a great deal of literature contradicts any claims that prolapse mesh kits improve efficacy outcomes. In the Weber study⁵¹ originally published in 2001 and reanalyzed by Chmielewski⁵² in 2011, repairs with polyglactin 910 mesh (absorbable) offered no advantage over traditional repairs regarding efficacy. The authors found no statistically or clinically significant differences between the groups in (a) the rate of prolapse beyond hymen, (b) the absence of pelvic organ prolapse symptoms, (c) reoperations for POP, and (d) all three outcomes combined. Stanford reviewed the literature on the success of native tissue anterior repairs compared to mesh-augmented repairs and found the success rates to be similar. Oversand⁵³ concluded that native tissue repairs for prolapse should be the first choice in treating primary POP because of low reoperation rates with excellent subjective and objective results and few complications. Funk and Visco⁵⁴ analyzed 27,809 prolapse surgeries from an insurance database and found that vaginal mesh and native tissue repair for anterior prolapse had similar 5-year risks for recurrent prolapse. The authors also determined that anterior vaginal wall prolapse was associated with an increased risk of any repeat surgery, which was driven by surgery for mesh removal

Regarding safety of mesh kits, there is a great deal of literature documenting the lifestyle-altering complications that occur with mesh repairs, including erosion, chronic pain syndromes, shrinkage and contraction causing vaginal shortening, tightening, and vaginal pain, infections, new onset stress urinary incontinence, and bladder and bowel dysfunction.

We are now seeing reports in the medical literature on large series of serious complications associated with vaginal mesh. For example, over a thousand patients with complications so severe as to require mesh removal surgery are described in these publications in recent years, written by surgeons usually in academic medical centers who are having to “clean up the mess”. These articles are coming from surgeons who perform these difficult mesh explant surgeries – often termed “salvage surgeries”. One such article termed this new field of medical practice, “Meshology”.⁵⁵

⁵¹ Weber, AM, et al. Anterior colporrhaphy: A randomized trial of three surgical techniques. Am J Obstet Gynecol. 2001 Dec;185(6):1299-304.

⁵² Chmielewski, L., et al. Reanalysis of a randomized trial of 3 techniques of anterior colporrhaphy using clinically relevant definitions of success. Am J Obstet Gynecol 2011;205:69.e1-8.

⁵³ Oversand, SH, et al. Long-term follow-up after native tissue repair for pelvic organ prolapse. Int Urogynecol J. 2014 Jan;25(1):81-9.

⁵⁴ Funk, MJ, et al. Long-term outcomes of vaginal mesh versus native tissue repair for anterior vaginal wall prolapse. Int Urogynecol J (2013) 24:1279–1285.

⁵⁵ Lee D, et al. Meshology: a fast-growing field involving mesh and/or tape removal procedures and their outcomes. Expert Rev Med Devices. 2015 Mar;12(2):201-16.

Another, Crosby (2014)⁵⁶ at the University of Michigan reported on 90 patients who received vaginal mesh and underwent removal surgery. The most common presenting signs and symptoms were: pelvic or vaginal pain, 64%; mesh exposure, 62%; a bulge sensation, 30%; and dyspareunia, 48% with most patients reporting more than one symptom. The authors found that only 51% of patients had complete resolution of all symptoms and pain was only treated successfully in 51% of patients. I reported a series of “salvage surgery”⁵⁷ following sling complications, also finding that sling removal surgery could be successful, but often required multiple surgeries. In my series, only 28% of women with pain as the presenting complaint considered the surgery a success. Hansen (2014)⁵⁸ at the University of Utah, reported a series of 111 women who were evaluated for complications associated with synthetic vaginal mesh. The most common complications were extrusion (65%), contraction (17%), and chronic pelvic pain (16%). The authors found that, despite their best efforts, two years after treatment (4.5 years after the index mesh surgery), women continued to report symptoms that negatively impacted their quality of life. These authors also found that the number of patients presenting with mesh complications increased every year of the study. In the companion article by Dunn (2014),⁵⁹ titled “Changed Women: The Long-Term Impact of Vaginal Mesh Complications,” the authors described the physical and emotional pain caused by mesh complications, including the feeling of hopelessness when they were informed that “there was nothing else we could do.”

Finally, Ethicon colluded with American Medical Systems, Inc. (AMS), C.R. Bard, Inc., and Boston Scientific Corporation (BSC) to influence reimbursement for mesh procedures, knowing that higher payments would increase usage of mesh products by hospitals and doctors. Ethicon participated in the formation of the Pelvic Health Coalition (PHC). The PHC consisted of a group of pro-mesh doctors selected by mesh manufacturers to influence reimbursement for mesh procedures.

The address of the PHC is the Washington, DC office of the Reed Smith law firm. I reviewed public and internal documents relating to the activities of the PHC. Reimbursement considerations were key to selling devices to hospitals and selling the procedure to physicians. Publicly, the PHC was “dedicated to raising awareness, particularly among elected Federal healthcare policy makers of the critical importance of pelvic health and to promote healthcare policy makers of the critical importance of pelvic health and to promote education about pelvic health issues. By dispelling myths and misunderstandings, the PHC is committed to improving the quality of life for women with pelvic health disorders.” However, internal documents make it clear that the group was formed to increase mesh payments. From Ethicon documents: “This is a coalition which we established at the ACOG meeting this year in Washington with the purpose

⁵⁶ Crosby, EC, et al. Symptom Resolution After Operative Management of Complications From Transvaginal Mesh. *Obstet Gynecol* 2014;123:134–9.

⁵⁷ Blaivas, J. G., et al. (2013). Salvage Surgery after Failed Treatment of Synthetic Mesh Sling Complications. *J Urol*. 2013 Oct;190(4):1281-6..

⁵⁸ Hansen, B, et al. Long-Term Follow-up of Treatment for Synthetic Mesh Complications. *Female Pelvic Med Reconstr Surg*. 2014 May-Jun;20(3):126-30.

⁵⁹ Dunn, et al., Changed Women: The Long-Term Impact of Vaginal Mesh Complications. *Female Pelvic Med Reconstr Surg* 2014;20: 131Y136.

being to improve hospital reimbursement for pelvic floor procedures which utilize synthetic or autologous products.”⁶⁰ PHC activities included:

- Publication of an article titled “Options, Best Techniques, and Coding Tips for Pelvic Prolapse Repair” in OB-GYN Management. BSC acknowledges that this “piece, along with the accompanying coding and billing scenarios, was initiated by BSC, AMS, J&J, and Bard through our participation in the Pelvic Health Coalition (PHC).”⁶¹
- Requesting the FDA to delay the 2008 Public Health Notification. The letter appears to be drafted by Industry; however, only physician names appear on the letterhead.⁶²
- Petitioning the Center for Medicare and Medicaid Services to give special status to mesh procedures.⁶³
- Removing language from an ACOG Technical Bulletin describing mesh procedures as “experimental” (Experimental procedures are typically not paid for by insurance companies and Medicare/Medicaid)⁶⁴

As a result of these efforts, “add-on” codes provided additional reimbursement to physicians for each piece of mesh used. Hospitals could use morbidity codes to obtain higher DRG⁶⁵ reimbursement for mesh operations. In my opinion, these pursuits involved the use of false and misleading information for financial gain and were undertaken with complete disregard for the safety of women who would be implanted with a Prolift device.

Based on my experience, my knowledge of the peer-reviewed medical literature, and my review of internal Ethicon documents, it is my opinion that the risks of the Prolift devices far outweigh any theoretical benefits.

All opinions are provided to a reasonable degree of medical certainty. I reserve the right to amend or supplement this report as new information becomes available.

This 1st day of February, 2016.

⁶⁰ ETH.MESH.00136420.

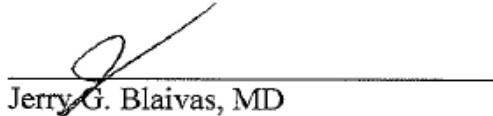
⁶¹ ETH.MESH.00738769; ETH.MESH.01280816; ETH.MESH.01280860; ETH.MESH.00720002.

⁶² ETH.MESH.02312097.

⁶³ CMS-1385-P-15007 (submission receipt, dated August 31, 2007 and accompanying letter); CMS billing; ETH.MESH.00720002.

⁶⁴ ETH.MESH.02316434.

⁶⁵ DRG: Diagnosis-related groups.



Jerry G. Blaivas, MD

V. FACTS OR DATA CONSIDERED IN FORMING OPINIONS

In addition to the references included herein, an Index is attached hereto and by reference made a part hereof. Please see **Exhibit "C"** attached.

VI. COMPENSATION

Dr. Blaivas' Fee Schedule is attached hereto and by reference made a part hereof. Please see **Exhibit "B"** attached.

VII. LISTING OF CASES IN WHICH TESTIMONY HAS BEEN GIVEN IN THE LAST FOUR YEARS

Merjem Delija v. Neil Sayegh, etc.; index no. 14449/2003

Jose Cuevas v. the Mount Sinai medical Center; Index no. 0017209/2004

Randy Smith, et al. v. Andrew Chan, M.D., et al.; Index No. 024786/2009

Katelyn Vercher, et al. v. Chiari Institute, et al.; 2:09-cv-01751-AKT

Lisa Marie Fontes, et al. v. American Medical Systems, Inc.; 2:12-CV-02472

Debbie Jilovec, et al., v. American Medical Systems, Inc.; 2:12-CV-05561

Joann Serrano, v. American Medical Systems, Inc.; 2:12-CV-3719

Mary Weiler, et al. v. American Medical Systems, Inc.; 2:12-CV-05836

Carolyn F. Smothers v. Boston Scientific Corp.; 2:12-cv-08016

Katherine L. Hall v. Boston Scientific Corp.; 2:12-cv-08186

Julia Wilson v. Boston Scientific Corp.; 2012-02626

Ronda Orozco, et al., v. Boston Scientific Corp.; 2012-03068

Maria Cardenas v. Boston Scientific Corp.; 2012-02912

Diane Albright v. Boston Scientific Corp.; 2012-00909

Jo Huskey, et. al v. Ethicon, Inc.; 2:12-cv-05201

Tonya Edwards, et. al v. Ethicon, Inc.; 2:12-cv-099

Exhibit A

Curriculum Vitae

Name: Jerry G. Blaivas, MD

Office Address: 445 East 77th Street
New York, NY 10075
Tele: (212) 772 3900

Citizenship: United States of America

Licensure: New York #144945, January 1981

Specialty
Certification: American Board of Urology, 1978

Education: Tufts University School of Medicine M.D., 1968
Tufts College, B.A., 1964

Post Graduate:

Intern, General Surgery: Boston City Hospital
Boston, MA
1968 - 1969

Resident, General Surgery: Boston City Hospital
Boston, MA
1969 - 1971

Resident, Urology: Tufts-New England Medical Center
Boston, MA
1973 - 1976

Military: Major, United States Army Department of Orthopedics
(Active Duty) Walson Army Hospital
Fort Dix, NJ
1971-1973

Faculty Appointments:
Adjunct Professor of Urology
SUNY Downstate Medical School
Brooklyn, NY
2008 - present

Clinical Professor of Urology

Weill Medical College of Cornell University
New York, NY
1993 - present

Professor of Clinical Urology
College of Physicians & Surgeons
Columbia University
New York, NY
1989 - 1993

Vice-Chairman, Department of Urology
College of Physicians & Surgeons
Columbia University
New York, NY
1987 - 1993

Director, Neurourology
College of Physicians & Surgeons
Columbia University
New York, NY
1981 - 1993

Associate Professor of Urology
College of Physicians & Surgeons
Columbia University
New York, NY
1981 - 1989

Associate Professor of Urology
Tufts University School of Medicine
Boston, MA.
1979 - 1981

Assistant Professor of Urology
Tufts University School of Medicine
Boston, MA.
1976 - 1979

Hospital and University

Administrative Appointments:

Chief of Urogynecology
Attending Surgeon (Urology)
Lenox Hill Hospital
New York, NY
1999 - 2007

Attending Surgeon (Urology)
The New York Presbyterian Hospital
New York, NY
1993 - present

Attending Urologist
The Presbyterian Hospital
New York, NY
1992 - 1993

Director, Neurourology Laboratory
The Presbyterian Hospital
New York, NY
1981 - 1993

Associate Attending Urologist
The Presbyterian Hospital
New York, NY
1981 - 1992

Chief of Urology
Helen Hayes Hospital
West Haverstraw, NY
1987 - 1993

Assistant Surgeon
New England Medical Center
Boston, Massachusetts
1976 - 1981

Director, Urodynamics Laboratory
New England Medical Center

Blaivas

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Boston, MA
1976 - 1981

Consultant in Urology
Massachusetts Rehabilitation Hospital
Boston, MA 1977 - 1981

Consultant in Urology
Braintree Hospital
Braintree, MA 1977 - 1981

Attending Physician, Surgical Service
Boston Veterans Administration Medical Center
Boston, MA
1977 – 1981

Professional Societies:

American Association of Genitourinary Surgeons
American Board of Urology
American College of Surgeons
American Urogynecologic Society
American Urologic Society, New York Section
American Urological Association
Chilean Urologic Society, Honorary Member
International Continence Society
Massachusetts Medical Society (1973 - 1981)
National Board of Medical Examiners
New York Academy of Medicine
Societe Internationale d'urologie
Society for Urodynamics and Female Urology
Society of Pelvic Surgeons
Society of University Urologists

Honors and Awards:

Victor A. Politano Award, American Urological Association, 2009

Jerry G. Blaivas Honorary Lectureship, Society of Urodynamics and Female Urology, established 2007

Continence Care Champion, National Association For Continence, 2005

Pfizer-American Urological Association Visiting Professor Award, 2004

The Best Clinical Study for the Year 2000.
Society for Urodynamics and Female Urology, 2000

Lifetime Achievement Award
Society for Urodynamics and Female Urology, 1999

Brantley Scott M.D. Award.
American Foundation for Urologic Disease, 1999.

J. Marion Sims Award
American Uro-Gynecologic Society, 1993

Best Doctors in America, 1992-present

Best Doctors in New York, 1992-present

Zimskind/Kendall Award
Urodynamic Society, 1985

First Prize for Research
Annual Meeting of the International
Continence Society, Leiden, 1982

Winner, Team Debate
Joint Meeting of the International
Continence Society and the Urodynamic
Society, Los Angeles, 1980

Commendations Medal
United States Army, 1973

Sword and Shield Honor Society
Tufts College, 1965

Hospital and University

Committees: Executive Committee
Department of Urology
College of Physicians & Surgeons
Columbia University, 1981-1993

Chairman, Quality Assurance Committee
Department of Urology
Columbia Presbyterian Medical Center
1986 - 1991

Committee on Computer Development for Medical Applications, The Presbyterian Hospital
1985 - 1993

Medical Evaluation Committee
Columbia Presbyterian Medical Center
1985 - 1987

Human Investigation Committee
Department of Urology
Columbia Presbyterian Medical Center
1981 - 1993

Chairman, Patient Care Committee
The Presbyterian Hospital
1981 - 1986

Executive Committee
Tufts University School of Medicine
1978 - 1981

Doctor's Office Committee
Columbia-Presbyterian Medical Center
1988 - 1993

Professional Committees:

Executive Committee
Society for Urodynamics and Female Urology
1999-present

Chairman, Voiding Dysfunction Committee
American Urological Association
1996-2000

Advisory Board Member

Blaivas

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New York Menopause Center
1996 - 2000

Bladder Health Council
American Foundation for Urologic Diseases
1996 - present

Guidelines Panel on Surgical Treatments for Female Urinary Incontinence American Urological Association
1994 - Present

Executive Committee
Urodynamics Society
1993-1999

Chairman New Technology Council
American Urological Association
1993 - 1997

Guest Examiner
American Board of Urology
1992 - 1996

President
Urodynamic Society
1992 - 1993

Member, BPH Guidelines Panel
Agency for Health Care & Policy Review
1989 - 1996

Technical Advisor
Incontinence Guideline Panel
Agency for Health Care & Policy Review
1989 - 1996

Practice Parameters & Guidelines Committee
American Urological Association
1991 - 1998

Member, Terminology Committee

Blaivas

8

American Urological Association
1991 - 1993

Chairman, Biomedical Engineering Committee
American Urological Association
1990 - 1993

Vice-Chairman, New Technology Committee
American Urological Association
1990 - 1993

Vice President
Urodynamic Society
1989 - 1991

Examination Committee
American Board of Urology
American Urological Association
1989 - 1993

Protocol Committee
Measurement Committee
AUA Cooperative BPH Study
1989 - 1993

Member, ad hoc Committee on Female Urology
American Urological Association
1988 - 1993

Advisory Board, Continence Program for Women
University of Virginia
1988 - 1996

Program Committee, Annual Meeting of the
American Urological Association
1988 - 1995

Patient Management Technology Committee
National Multiple Sclerosis Foundation
1987 - 1991

Blaivas

9

Secretary, Urodynamic Society
1986 - 1989

National Metric Council - Representative from the
American Urological Association
1986 - 1991

Chairman, Urology Sub-Committee
American Society for Testing and Materials
1986 - 1991

Co-Chairman, Annual Urodynamic Society Meeting
1985

Program Committee, Combined Meeting of the
International Continence Society and the
Urodynamic Society
1985

Vice-Chairman, Urology Sub-Committee
American Society for Testing and Materials
1985 - 1986

Program Committee, Annual Meeting of the
American Urological Association
1984 - 1986

Standardization Committee
International Continence Society
1983 - 1991

Medical Advisory Board, New York Chapter
National Multiple Sclerosis Foundation
1983 - 1991

Member-at-large
Executive Committee, Urodynamic Society
1982 - 1984

Program Chairman
Annual Urodynamic Society Meeting, Boston

Blaivas

10

1981

Chairman, Nomenclature Committee
Urodynamic Society
1980-1985

Education Committee
National Multiple Sclerosis Foundation
1980 - 1990

Neurophysiology Committee
Urodynamic Society
1980 - 1986

Program Committee, Combined Meeting of the
International Continence Society and the
Urodynamic Society
1980

Biomedical Engineering Committee
American Urological Association
1980 - 1993

Chairman, Task force on Urodynamic Procedures
Urodynamic Society
1980 – 1984

Editorial Positions: Editor-in-Chief, *Neurourology and Urodynamics*
1981 - 2007

Editorial Boards: **Neurourology & Urodynamics** 1981 - present
 Contemporary Urology 1998 - 2007
 International Urogynecology Journal 2002 - present

Reviewer: British Journal of Urology
International Urogynecology Journal
Journal of Urology
Urology
Obstetrics & Gynecology
The New England Journal of Medicine
American Journal of Physiology

Brain
Neurology

Consulting Committee: Urologia Integrada y de Investigacion

Previous Grant Support:

Smith Kline Beecham 1993 - 1995	Effects of once daily dosing with two dose levels of epristeride or placebo on the voiding detrusor pressure in patients with bladder outflow obstruction due to benign prostatic hyperplasia.
Eli Lilly 1993 - 1995	Duloxetine vs. placebo in patients with urinary incontinence - assessment of subjective & objective parameters. \$92,500
American Foundations Of Urologic Diseases Scholar Award (Faculty Sponsor) 1988 - 1990	Parameters of Detrusor Contractility \$50,000
National Multiple Sclerosis Society 1977 – 1978	The Diagnosis, Treatment and National History of Voiding Disturbances in Multiple Sclerosis Grant # RG1108-A-1 \$78,418
National Multiple Sclerosis Society 1978 – 1980	The diagnosis, treatment and national history of voiding disturbances in multiple sclerosis. Grant # RT1108-B-2 \$113,915
Merrell Research Center 1978	Effect of Oral Candicidin on on Benign Prostatic Hypertrophy, \$52,000
Smith, Klein & French 1982	Dose Range Study of Phenoxybenzamine in Benign

	Prostatic Hypertrophy \$27,000
Eastern Paralyzed Veterans 1983 - 1984 Grant \$100,000	NeuroUrology Fellowship
Eastern Paralyzed Veterans 1984 - 1985 Training Grant \$17,000	Neurourology Nurse
Roerig Pharmaceuticals 1984 - 1985	Geocillin in the Treatment of Recurrent Urinary Tract Infections Study # 83-R-003 \$25,000
Roerig Pharmaceuticals 1985-1986	Geocillin for the Treatment of Bacterial Prostatitis in Patients with Multiple Sclerosis or Spinal Cord Injuries with Associated Dysfunctional Urinary Bladders Study # 84-R-014 \$18,000
American Federation For Aging (AFAR) 1987 - 1988	Urodynamics of Aging AFAR CU50384501 \$16,000
Embassy Arab Republic of Egypt Cultural and Educational Bureau Peace Fellowship Program	Bladder Outlet Obstruction PF # 2436 - \$17,000
Spinal Cord Research Parameters of Bladder Foundation 1989 – 1990	Contractility in an In-vitro Rabbit Bladder Model, \$19,200
National Multiple 1988 - 1991	Neurourodynamic Evaluation Sclerosis Foundation of Multiple Sclerosis Grant # RG1997-A-4

\$116,682

PUBLICATIONS

Articles in Peer Review Journals:

1. **Blaivas JG**, Pais, VM, Spellman, RM. Chemolysis of Residual Stone Fragments After Extensive Surgery for Staghorn Calculi. *Urology* 6:680-6, 1975.
2. **Blaivas JG**, Pais VM, Retik AB. Paraurethral Cysts in the Female Neonate. *Urology* 7:504-7, 1976.
3. **Blaivas JG**, Previte SR, Pais VM. Idiopathic Pelviureteric Varices. *Urology* 9:207-1, 1977.
4. **Blaivas JG**, Labib KB, Bauer SB, Retik AB. A New Approach to Electromyography of the External Urethral Sphincter. *J Urol* 117:773-7, 1977.
5. **Blaivas JG**, Labib KB, Bauer SB, Retik AB. Changing Concepts in the Urodynamic Evaluation of Children. *J Urol* 117:778-3, 1977.
6. **Blaivas JG**, Labib, KB. Urinary Retention in the Female: Complete Urodynamic Evaluation. *Urology* 10:383, 1977.
7. Rao CN, **Blaivas JG**. Primary Renal Artery Dissecting Aneurysms, A review. *J Urol* 118:716-9, 1977.
8. Labib KB, Bauer SB, **Blaivas JG**. External Sphincter Electromyography in a Comprehensive Urodynamic Evaluation. *Archives Phys Med & Rehab*, 58:521, 1977.
9. **Blaivas JG**, Labib KB, Scott RM. Urodynamic Evaluation as neurologic test of Sacral Cord Function. *Urology* 9:682, 1979.
10. **Blaivas JG**, Bhimani G, Labib KB. Vesicourethral Dysfunction in Multiple Sclerosis. *J Urol* 122:342-7, 1979.
11. **Blaivas JG**, Labib KB, Michalik SJ, Zayed AAH. Failure of Bethanechol Denervation Supersensitivity as a Diagnostic Aid. *J Urol* 123:199, 1980.
12. **Blaivas JG**, Labib KB, Michalik SJ, Zayed AAH. Cystometric Response to Propanetheline in Detrusor Hyperreflexia: Therapeutic Implications. *J Urol* 124:259, 1980.
13. **Blaivas JG**. Management of Bladder Dysfunction in Multiple Sclerosis. *Neurology* 30(2):12, 1980.

14. **Blaivas JG**, O'Donnell TF, Gottlieb P, Labib KB. Comprehensive Laboratory Evaluation of Erectile Dysfunction. *J Urol* 124:201,1980.
15. **Blaivas JG**, Sinha HPM, Zayed AAH, Labib KB. Detrusor External Sphincter Dyssynergia, *J Urol* 125:542-4,1981.
16. **Blaivas JG**, Sinha HPM, Zayed AAH, Labib KB. Detrusor External Sphincter Dyssynergia: A detailed EMG study. *J Urol* 125:545-8,1981.
17. **Blaivas JG**, Fisher DM. Combined Radiographic and Urodynamic Monitoring: Advances in Technique. *J Urol* 125:693-4,1981.
18. **Blaivas JG**, Zayed AAH, Labib KB. The Bulbocavernosus Reflex in *Urology*: A Prospective Study of 299 Patients. *J Urol* 126:197-9,1981.
19. **Blaivas JG**. The Neurophysiology of Micturition. *J Urol* 127:958-3,1982.
20. **Blaivas JG**, Awad SA, Bissada N, Khanna OP, Krane RJ, Wein AJ, et al. Urodynamic Procedures: Recommendations of the Urodynamic Society. 1. Procedures Which Should be Available for Routine Urologic Practice. *Neurourol Urodyn* 1:51-5,1982.
21. Sant GR, Heaney JA, Parkhurst EC, **Blaivas JG**. Obstructive Uropathy. A Potentially Serious Complication of Reconstructive Vascular Surgery. *J Urol* 129:16-2,1982.
22. Barbalias GA, **Blaivas JG**. Neurologic Implications of the Pathologically Open Bladder Neck. *J Urol* 129:780-3,1983.
23. Zinner NR, Susset, J, Coolseat BRLA, Griffiths D, Jonas U, Sterling AM, **Blaivas JG**, et al. Great Debate Resolved: The Urethral Closure Pressure Profile Should be Used For Diagnosis and Management of Female Stress Incontinence. *Neurourol Urodyn* 2:81-99,1983.
24. **Blaivas JG**, Barbalias GA. Characteristics of Neural Injury After Abdominal Perineal Resection. *J Urol* 129:84-7,1983.
25. Sant G, **Blaivas JG**, Meares EM. Hemiacidrin Irrigation in the Management of Struvite Calculi: Long Term Results. *J Urol* 130:1048-50,1983.
26. Norlen LJ, **Blaivas JG**, Gable H. Cystopathy in Patients With Severe Diabetic Nephropathy. Diabetic Nephropathy,1983.

27. **Blaivas JG.** Sphincter Electromyography. *Neurourol Urodyn* 2:269-88,1983.
28. Katz GP, **Blaivas JG.** A Diagnostic Dilemma: When Urodynamic Findings Differ From the Clinical Impression. *J Urol* 129:1170-4,1983.
29. Norlen LJ, **Blaivas JG**, Grodin W, Lundberg JM. Contractile Effect of Substance P on the Canine Urinary Bladder In Vivo. *Neurourol Urodyn*, 2:323-7,1983.
30. **Blaivas JG**, Barbalias GA. Detrusor External Sphincter Dyssynergia in Men With Multiple Sclerosis: An Ominous Urological Condition. *J Urol* 131:91-4,1984.
31. Barbalias GA, **Blaivas JG**, Klauber G. Critical Evaluation of the Crede Maneuver: A Urodynamic Study of 207 Patients. *J Urol* 131:91-4,1984.
32. **Blaivas JG.** Multichannel Urodynamic Studies. *Urology* 23:421-38,1984.
33. Sawczuk I, **Blaivas JG.** Successful Surgical Treatment of Giggle Incontinence. *Neurourol Urodyn* 3:63,1984.
34. **Blaivas JG.** Urodynamic Diagnosis of Primary Bladder Neck Obstruction. *World J Urol* 2:191,1984.
35. Oliver LM, **Blaivas JG**, McGuire E, Susset, J. Functional Vaginal Electrical Stimulation (FVES) for the Treatment of Frequency and Incontinence in Women. Proceedings of the Urodynamic Society, p47,1984.
36. **Blaivas JG**, Salinas J. Type III Stress Urinary Incontinence: The Importance of Proper Diagnosis and Treatment. *Surgical Forum* 35:472,1984.
37. **Blaivas JG.** Salinas J., Katz P. Role of Urodynamic Testing in the Evaluation of Subtle Neurourological Lesions. *Neurourol Urodyn* 4:211-8,1985.
38. Abrams P, **Blaivas JG**, Stanton SL, Andersen J, Fowler CJ, Gerstenberg T, et al. Sixth Report on the Standardisation of Terminology of Lower Urinary Tract Function. Procedures Related to Neurophysiological Investigations: Electromyography, Nerve Conduction Studies, Reflex Latencies, Evoked Potentials and Sensory Testing. The International Continence Society on Standardisation of Terminology, New York, *Scand J Urol Nephrol* 20:161-4,1986
39. Norlen L, **Blaivas JG.** Unsuspected Proximal Urethral Obstruction. *J Urol* 135:972-6,1986.
40. Salinas J, Berger Y, De La Rocha RE, **Blaivas JG.** Urologic Evaluation in the Shy- Drager Syndrome. *J Urol* 135:741-3,1986.

41. Abrams P, Andersen JT, **Blaivas JG**, Stanton SS. Sixth Report of the Standardization of Terminology of Lower Urinary Tract Function: Procedures Related to Neurophysiologic Investigations. *Neurourol Urodyn* 5:373-9,1986.
42. Axelrod SA, **Blaivas JG**. The Distinction Between Poor Detrusor Contractility and Bladder Outlet Obstruction. Proceedings of the International Continence Society. Boston, 1986.
43. Axelrod SA, **Blaivas JG**. Bladder Neck Obstruction in Women. *J Urol* 137:497-9,1987.
44. BergerY, **Blaivas JG**, De La Rocha RE, Salinas JM. Urodynamic Findings in Parkinson's Disease. *J Urol* 138:836-8,1987.
45. Abrams P, **Blaivas JG**, Stanton SL, Andersen J, Fowler CJ, Gerstenberg T, Murray K. Sixth Report on the Standardization of Terminology of Lower Urinary Tract Function. Procedures Related to Neurophysiological Investigations: Electromyography, Nerve Conduction Studies, Reflex Latencies, Evoked Potentials and Sensory Testing. The International Continence Society, *Br J Urol* 59:300-4,1987.
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47. Sarky MS, **Blaivas JG**. Functional Types of Prostatic Obstruction. *Neurourol Urodyn* 7:221-2,1988.
48. Sarky MS, **Blaivas JG**. Low-Pressure Low-Flow Syndromes. A Computer Based Classification on Functional Basis. *Neurourol Urodyn* 7:225-6,1988.
49. Sarky MS, **Blaivas JG**, Schussler G. Bladder Outlet Conductance: Evolution, Normal and Obstructive Patterns. *Neurourol Urodyn* 7:223-4,1988.
50. **Blaivas JG**. Pathophysiology and Differential Diagnosis of Benign Prostatic Hypertrophy. *Urology* 32:supp5-11,1988.
51. Abrams P, **Blaivas JG**, Stanton SL, Andersen JT. The Standardisation of Terminology of Lower Urinary Tract Function. *Neurourol Urodyn* 7:403-26,1988.
52. Kaplan SA, **Blaivas JG**. Diabetic Cystopathy. *J Diabet Complic* 2:133-9,1988.
53. **Blaivas JG**. Vaginal Flap Urethral Reconstruction: An Alternative to Bladder Flap Neourethra. *J Urol* 141:542-5,1989.

54. Kaplan SA, Brown WC, **Blaivas JG**. Parameters of Detrusor Contractility: Effects of Hysteresis and Bladder Volume in an In-Vitro Whole Rabbit Model. *Surgical Forum*, Volume XL 665-6, 1989.
55. Kaplan SA, **Blaivas JG**, Brown WC, Schuessler G. Parameters of Detrusor Contractility: The Effect of Bladder Volume and Outlet Resistance on Qmax, Power and Work in In-Vitro Whole Rabbit Model. *Neurourol Urodyn* 8:375-6, 1989.
56. **Blaivas JG**. Diagnostic Evaluation of Urinary Incontinence. *Urology* 36:4, 1990.
57. Berger Y, Salinas JN, **Blaivas JG**. Urodynamic Differentiation of Parkinson's Disease and the Shy Drager Syndrome. *Neurourol Urodyn* 9:117-1, 1990.
58. Berger Y, **Blaivas JG**, Oliver L. Urinary Dysfunction in Transverse Myelitis. *J Urol* 144:103-5, 1990.
59. **Blaivas JG**. Surgical Treatment of Urinary Incontinence in 223 Consecutive Women. *Neurourol Urodyn* 9:401-2, 1990.
60. Chancellor MB, Otter MW, Kaplan SA, **Blaivas JG**. A New Method of Measuring Uroflow in the Rat Bladder. *Neurourol Urodyn* 9:391-2, 1990.
61. **Blaivas JG**. Diagnostic Evaluation of Incontinence in Patients with Neurologic Disease, *J Am Geriatr Soc* 38:306-0, 1990.
62. Kaplan SA, **Blaivas JG**, Brown WC, Levin RM. Parameters of Detrusor Contractility: The Effect of Hysteresis, Electrical Stimulation and Bladder Volume in an In-Vitro Whole Rabbit Model. *Neurourol Urodyn* 10:53-9, 1991.
63. **Blaivas JG**. Diagnostic Evaluation of Incontinence. *Urology* 36:supp11-20, 1991.
64. Chancellor MB, **Blaivas JG**, Axelrod S, Kaplan SA. Bladder Outlet Obstruction Versus Impaired Detrusor Contractility: The Role of Uroflow. *J Urol* 145:810-2, 1991.
65. Luangkhot R, Peng B, and **Blaivas JG**. Ileocecocystoplasty for the Management of Refractory Neurogenic Bladder: Surgical Technique and Urodynamic Findings. *J Urol* 146:1340-4, 1991.
66. **Blaivas JG**, Jacobs BZ. Pubovaginal Sling for the Treatment of Complicated Stress Incontinence. *J Urol* 145:1214-8, 1991.
67. Kaplan SA, **Blaivas JG**, Chancellor MB. Bladder and Sphincter Behavior in Patients with Spinal Cord Injury. *J Urol* 146:113-7, 1991.

68. Chancellor MB, **Blaivas JG**, Levin RM, Kaplan SA, Otter MW, Schussler G. New Method of Measuring Uroflow in the Rat Bladder. *Neurourol Urodyn* 11:123-9,1992.
69. Andersen JT, **Blaivas JG**, Cardozo L, Thuroff J. Lower Urinary Tract Rehabilitation Techniques: Seventh Report on the Standardization of Terminology of Lower Urinary Tract Function. *Neurourol Urodyn* 11:593-3,1992
70. Barry MJ, Fowler FJ, O'Leary MP, Bruskewitz RC, Holtgrewe HL, Meburst WK, AUA Measurement Committee. Correlation of the American Urological Association Symptom Index with Self-Administered Versions of the Madsen-Iversen, Boyarsky and Maine Medical Assessment Program Symptom Indexes. *J Urol* 148:1558-3,1992.
71. Chancellor MB, Kaplan SA, **Blaivas JG**. The Cholinergic and Purinergic Components of Detrusor Contractility in a Whole Rabbit Bladder Model. *J Urol* 148:906-9,1992.
72. Grino PB, Bruskewitz R, **Blaivas JG**, et al. Maximum Urinary Flow Rate by Uroflowometry: Automatic or Visual Interpretation. *J Urol* 149:339-1,1993.
73. Kaplan SA, Shabsigh R, Soldo KA, **Blaivas JG**, Olsson CA. Transrectal Hyperthermia in the Management of Men with Prostatism: An Algorithm for Therapy. *J Urol* 72:195-0,1993.
74. Chancellor MB, **Blaivas JG**, Kaplan SA, Axelrod S. Letter to the Editor Re: Bladder Outlet Obstruction Versus Impaired Detrusor Contractility: The Role of Uroflow. *J Urol* 149:378-9,1993.
75. Chaikin DC, **Blaivas JG**, et al. Behavioral Therapy for the Treatment of Refractory Interstitial Cystitis. *J Urol* 149:1445-8,1993.
76. Gardner TA, Poppas DP, Wei JT, **Blaivas JG**. Volvulus of the Ileal Conduit: A Late Complication. *J Urol* 152:948-50,1994.
77. Seaman EK, Jacobs BZ, **Blaivas JG**, Kaplan SA. Persistence or Recurrence of Symptoms after Transurethral Resection of the Prostate: A Urodynamic Assessment. *J Urol* 152:935-7,1994.
78. Santarosa RP, **Blaivas JG**. Peiurethral Injection of Autologous Fat for the Treatment of Sphincteric Incontinence. *J Urol* 151:607-1,1994.
79. **Blaivas JG**. Urinary Incontinence After Radical Prostatectomy. *Cancer* 75:7,1995.
80. Heritz DM, Romanzi LJ, **Blaivas JG**. The Surgery of Vesico-Vaginal Fistula: Early vs. Late, Abdominal vs. Vaginal Repair. *J Urol* 153:1110-3,1995.

81. Kaplan SA, Te AE, **Blaivas JG**. Urodynamics Findings in Patients With Diabetic Cystopathy. *J Urol* 153:342-4,1995.
82. Mulcahy JJ, Kirkemo, AK, Rudy DC, **Blaivas JG**, Wahle GR, et al. Efficacy and Safety of Duloxetine in Stress Incontinence Patients. *Neurourol Urodyn* 15:395-9,1996.
83. **Blaivas JG**, Heritz DM. Vaginal Flap Reconstruction of the Urethra and Vesical Neck in Women: A Report of 49 Cases. *J Urol* 155:1014-7,1996.
84. **Blaivas JG**. Obstructive uropathy in the male. *Urol Clin North Am* 23:373-84,1996.
85. **Blaivas JG**, Heritz DM. Physiological Principles for Surgical Correction of Detrusor Dysfunction. *J EndoUrology* 10:3,1996.
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88. **Blaivas JG**, Appell RA, Fantl JA, Leach G, McGuire EJ, Resnick NM, Raz S, Wein AJ. Definition and Classification of Urinary Incontinence: Recommendations of the Urodynamic Society. *Neurourol Urodyn* 16:149-1,1997.
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90. Chaikin DC, Rosenthal J, **Blaivas JG**, Pubovaginal Fascial Sling for All Types of Stress Urinary Incontinence: Long-term Analysis. *J Urol* 160: 1312-6,1998.
91. Weiss JP, **Blaivas JG**, Stember DS, Brooks, MM, Nocturia in Adults: Etiology and Classification. *Neurourol Urodyn* 17:467-2,1998.
92. **Blaivas JG**, Stember DS, Weiss JP. Etiology of Voiding Symptoms in Men: Correlation of Individual AUA Symptom Scores with Urodynamic and Diary Parameters. *Neurourol Urodyn* 17:398-9,1998.
93. Chaikin DC, Romanzi LJ, Rosenthal J, Weiss JP, **Blaivas JG**. The Effects of Genital Prolapse on Micturition. *Neurourol Urodyn* 17:426-7,1998.

94. Lemer ML, Chaikin DC, **Blaivas JG**. Augmentation Cystoplasty and Urinary Diversion for the Treatment of Neurogenic Bladder. *Neurourol Urodyn* 17:344,1998.
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99. Weiss JP, **Blaivas JG**, Stember DS, Chaikin DC. Evaluation of the Etiology of Nocturia in Men: The Nocturia and Nocturnal Bladder Capacity Indices. *Neurourol Urodyn* 18:559-5,1999.
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101. Lemer ML, Chaikin DC, **Blaivas JG**. Tissue Strength Analysis of Autologous and Cadaveric Allografts for the Pubovaginal Sling. *Neurourol Urodyn* 18:497-3,1999.
102. Groutz A, **Blaivas JG**, Fait G, Sassone AM, Chaikin DC, Gordon D. The Significance of the American Urological Association Symptom Index Score in the Evaluation of Women with Bladder Outlet Obstruction. *J Urol* 163:207-1,2000.
103. Groutz A, **Blaivas JG**, Chaikin DC. Bladder Outlet Obstruction in Women: Definition, Prevalence and Characteristics. *Neurourol Urodyn* 19:213-0,2000.
104. Groutz A, Chaikin DC, **Blaivas JG**. Predicting the Need for Anti-Incontinence Surgery in Continent Women Undergoing Repair of Severe Urogenital Prolapse. *J Urol* 163:531-4,2000.
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- Transurethral Catheter. *J Urol* 164:109-4, 2000.
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112. **Blaivas JG**. Issues of uroselectivity in male and female Luts. Summary of the meeting. *Br J Urol* 86, 2 supp: 55, 2000.
113. Romanzi LJ, **Blaivas JG**. Protracted urinary retention necessitating urethrolysis following tension-free vaginal tape surgery. *J Urol* 164:2022-3. 2000
114. **Blaivas JG**, Groutz A, Verhaaren M. Does the method of cystometry affect the incidence of involuntary detrusor contractions? A prospective randomized urodynamic study. *Neurourol Urodyn* 20:141-5, 2001.
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Symptoms with Urodynamic Findings. *J Urol* 166:550-3, 2001.

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123. Sakamoto K, Weiss JP, **Blaivas JG**, Versi E. Cystometric and voiding diary-based bladder capacity in male and female patients with nocturia. *J Urol* 165:supp 298, 2001.
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Clinical Approaches, Springer, New York, 2012

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1. Universitas Complutensas (Madrid)
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12. Beth Israel Medical Center (New York)
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16. Albany Medical College, 2001
17. University of Toronto, 2003
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Jerry G. Blaivas, MD, FACS
Biographical Sketch

Dr. Blaivas is an internationally renowned urologist with over thirty years of clinical experience. He is, as well, an acclaimed academician, educator, writer and editor with an unimpeachable reputation for honesty and compassion. His clinical expertise ranges from office urology to the most complicated and difficult surgical problems. Known as a “doctor’s doctor,” he is considered the “doctor of last resort” by patients and doctors alike when they experience multiple failed treatments.

Dr. Blaivas is Clinical Professor of Urology at Weill Cornell Medical College, Adjunct Professor at SUNY Downstate and Attending Surgeon at New York Presbyterian Hospital and Lenox Hill Hospital. He is former Professor of Urology and Vice Chairman of the Department of Urology at Columbia University College of Physicians and Surgeons.

In addition to a widely acclaimed expertise in routine urologic conditions such as prostate problems in men, pelvic organ prolapse (dropped bladder) in women and incontinence in both sexes, Dr. Blaivas was one of the originators of urodynamics and pioneered many of the current surgical procedures to correct stress incontinence, urinary fistulas, urethral diverticulum, overactive bladder and neurogenic bladder. He is one of the few surgeons who routinely performs reconstructive surgery for prolapse and incontinence without the use of mesh and has published one of the largest series in the world on treatment of mesh complications. He has a particular interest and expertise in complex urologic problems – complications of radiation and prostate surgery, failed incontinence surgery and failed prolapse surgery.

Dr. Blaivas is former President of the Urodynamics Society and the recipient of numerous awards, including the Lifetime Achievement Award from the Society for Urodynamics and Female Urology, the Victor A. Politano Award from the American Urological Association, the F. Brantley Scott M.D. Award from the American Foundation for Urologic Disease, the J. Marion Sims Award from the American Uro-Gynecologic Society and the Paul Zimskind Award from the Urodynamic Society.

In addition, Dr. Blaivas has consistently been listed in *New York Magazine’s Best Doctors* and Castle Connolly’s *America’s Top Doctors* and *Top Doctors: New York Metro Area* from the publications’ inception in 1992 to the present.

Dr. Blaivas is the Founder of the major scientific journal *Neurourology & Urodynamics* and was Editor-in-Chief from 1982-2006. He is on the editorial board of *Contemporary Urology* and *International Urogynecology Journal* and is a reviewer for a number of other journals, including the *Journal of Urology*, *Urology*, *The New England Journal of Medicine*, and *British Journal of Urology*. He is the primary author of over 400 peer review scientific articles, book chapters and reviews and has edited seven books. He is a member of numerous professional societies, including the American Association of Genitourinary Surgeons, Society of Pelvic Surgeons, American Urological Association, American College of Surgeons, Society for Urodynamics and Female Urology, American Urogynecologic Society, and the International Continence Society.

Dr. Blaivas founded the not-for-profit organization, the Institute for Bladder and Prostate Research, which is dedicated to research relating to the lower urinary tract and female genital tract, including urinary incontinence, prostate conditions, neurogenic bladder, interstitial cystitis and genital prolapse. In addition, he is the author of a book for the lay public on bladder and prostate conditions entitled, *Conquering Bladder and Prostate Problems; an Authoritative Guide for Men and Women*.

Exhibit B

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November 1, 2012

Margaret M. Thompson, MD JD MPAFF
Mueller Law
404 W. 7th Street
Austin, TX 78701

Re: Dr. Blaivas' fee schedule

To whom it may concern:

Per your request, I have set forth Dr. Blaivas' fee schedule below. Please be advised that **fees are required prior to or at the time of service.**

\$750 per hour for review of medical records and preparation of reports.

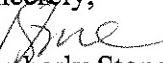
\$7,500 for a half day of deposition testimony, trial testimony and/or consultations with attorney, (including travel time)

\$15,000 for a full day of deposition testimony, trial testimony and/or consultations with attorney, (including travel time)

Given the nature of Dr. Blaivas' practice, he must be notified well in advance of any cancellation. Otherwise the above fee schedule will apply.

Please confirm your agreement to the above terms by signing below.

Sincerely,


Kimberly Stone

Addressee *Sign*

Addressee *Print*

Exhibit C

Document Date	Title	Primary Author	Publication
2013-00-00	Correction: Anterior Colporrhaphy versus Transvaginal Mesh for Pelvic-Organ Prolapse		N ENGL J MED 368;4:394
2012-00-00	GUIDE TO LEARNING IN FEMALE PELVIC MEDICINE AND RECONSTRUCTIVE SURGERY		
	Evaluation and Management of Complications From Synthetic Mesh After Pelvic Reconstructive Surgery: A Multi-Center Study	Abbot, et al	Presentation Number: Paper 29
2014-01-01	Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study	Abbott, et al	Am J Obstet Gynecol 2014;210:163.e1-8
2011-01-01	Single-Incision Mini-Slings Versus Standard Midurethral Slings in Surgical Management of Female Stress Urinary Incontinence: A Meta-Analysis of Effectiveness and Complications	Abdel-Fattah, et al	European Urology 60 (2011) 468 - 480
2006-01-01	How common are tape erosions? A comparison of two versions of the transobturator tension-free vaginal tape procedure	Abdel-Fattah, et al	BJU Int, 98(3), 594-598
2008-01-01	Retrospective multicentre study of the new minimally invasive mesh repair devices for pelvic organ prolapse	Abdel-Fattah, et al	BJOG 2008;115:22–30
	A RANDOMISED PROSPECTIVE SINGLE-BLINDED STUDY COMPARING "INSIDE-OUT" VERSUS "OUTSIDE-IN" TRANSOBTURATOR TAPES IN THE MANAGEMENT OF FEMALE STRESS URINARY INCONTINENCE (E-TOT STUDY); 3 YEARS FOLLOW-UP.	Abdel-fattah, et al	Poster 18
2010-01-01	Evaluation of transobturator tapes (E-TOT) study: randomised prospective single-blinded study comparing inside-out vs. outside-in transobturator tapes in management of urodynamic stress incontinence: Short term outcomes	Abdel-fattah, et al	European Journal of Obstetrics & Gynecology and Reproductive Biology 149 (2010) 106-111

2010-04-12	Randomised prospective single-blinded study comparing 'inside-out' versus 'outside-in' transobturator tapes in the management of urodynamic stress incontinence: 1-year outcomes from the E-TOT study	Abdel-fattah, et al	BJOG 2010;117:870—878
2010-05-18	Tension-Free Vaginal Tape versus Secure Tension-Free Vaginal Tape in Treatment of Female Stress Urinary Incontinence	Abdelwahab, et al	Current Urology, 4(2), 93-98
2011-01-01	Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials; a systematic review	Abed, et al	Int Urogynecol J (2011) 22:789–798
2011-01-01	Treatment of moderate to severe female stress urinary incontinence with the adjustable continence therapy (ACT) device after failed surgical repair	Aboseif, et al	World J Urol (2011) 29:249—253
	Outcome of treatment of anterior vaginal wall prolapse and stress urinary incontinence with Transobturator tension-free vaginal mesh (Prolift) and concomitant tension-free vaginal tape-obturator.	Abou-Elela A, et al.	Adv Urol. 2009;341268. Epub 2008 Dec 25.
2011-00-00	Is Tissue Engineering and Biomaterials the Future for Lower Urinary Tract Dysfunction (LUTD)/Pelvic Organ Prolapse (POP)?	Aboushwareb, et al	Neurourology and Urodynamics 30:775--782 (2011j)
2009-01-01	Tissue mechanics, animal models, and pelvic organ prolapse: A review	Abramowitch, et al	European Journal of Obstetrics & Gynecology and Reproductive Biology 144S (2009) S146–S158
2011-01-01	Synthetic Vaginal Tapes for Stress Incontinence: Proposals for Improved Regulation of New Devices in Europe	Abrams, et al	European Urology 60:1207-1211
2006-12-01	ACOG Committee Opinion Number 352: Innovative Practice: Ethical Guidelines	ACOG	ACOG Committee Opinion No. 352

	ACOG Committee Opinion No. 513: vaginal placement of synthetic mesh for pelvic organ prolapse.	ACOG	Obstet Gynecol. 2011;118:1459–1464.
2007-02-01	ACOG PRACTICE BULLETIN NUMBER 79: CLINICAL MANAGEMENT GUIDELINES FOR OBSTETRICIAN-GYNECOLOGISTS	ACOG	The American College of Obstetrics & Gynecology
2007-09-01	ACOG PRACTICE BULLETIN NUMBER 85: CLINICAL MANAGEMENT GUIDELINES FOR OBSTETRICIAN -GYNECOLOGISTS NUMBER 85	ACOG	The American College of Obstetricians and Gynecologists
2005-06-01	ACOG Practice Bulletin Number 63: Clinical Management Guidelines for Obstetrician-Gynecologists	Acog Committee on Practice Bulletins--Gynecology	Obstet Gynecol
2008-10-01	A Randomized Comparison of Two Synthetic Mid-Urethral Tension-Free Slings	Agarwala N	UroToday International Journal / Vol 1 / Iss 4/
2007-01-01	Laparoscopic sacral colpopexy with Gynemesh as graft material-Experience and results	Agarwala, et al	Journal of Minimally Invasive Gynecology (2007) 14, 577–583
2014-01-01	Functional outcomes following surgical management of pain, exposure or extrusion following a suburethral tape insertion for urinary stress incontinence	Agnew, et al	Int Urogynecol J (2014) 25:235–239
2006-00-00	Mesh migration following repair of inguinal hernia: a case report and review of literature	Agrawal, Avill	Hernia (2006) 10: 79–82
2011-01-01	Long term patient satisfaction after suburethral sling operation for stress incontinence	Al-Omary, Atalla	Int Urogynecol J (2011) 22 (Suppl 3):
2007-01-01	Burch Colposuspension versus Fascial Sling to Reduce Urinary Stress Incontinence	Albo, et al	N Engl J Med 2007;356:2143-55
2012-12-01	Treatment Success of Retropubic and Transobturator Mid Urethral Slings at 24 Months	Albo, et al	J Urol Vol. 188, 2281-2287
2009-00-00	Isolation of fibroblasts for coating of meshes for reconstructive surgery: differences between mesh types	Albrich, et al	Regenerative Medicine
2003-01-02	Use of Cadaveric Fascia Lata To Correct Grade IV Cystocele	Almeida,et al	International Braz J Urol Vol. 29 (1): 48-52

	Two-year outcomes after vaginal prolapse reconstruction with mesh pelvic floor repair system.	Alperin M, et al.	Female Pelvic Med Reconstr Surg. 2013; 19(2):72-78.
	Perioperative outcomes of the Prolift pelvic floor repair systems following introduction to a urogynecology teaching service.	Alperin M, et al.	Int Urogynecol J. 2008;19:1617-1622.
2011-01-01	Anterior Colporrhaphy versus Transvaginal Mesh for Pelvic-Organ Prolapse	Altman, et al	N Engl J Med 2011;364:1826-36
2007-02-01	Perioperative Morbidity Using Transvaginal Mesh in Pelvic Organ Prolapse Repair	Altman, et al	Obstet Gynecol 2007;109:303-8
	INTRA- AND PERIOPERATIVE MORBIDITY FOLLOWING PELVIC ORGAN PROLAPSE REPAIR USING A TRANSVAGINAL SUTURE CAPTURING MESH DEVICE COMPARED TO TROCAR GUIDED TRANSVAGINAL MESH AND TRADITIONAL COLPORRAPHY	Altman, et al	Abstract
	Short-term outcome after transvaginal mesh repair of pelvic organ prolapse.	Altman, et al	Int Urogynecol J. 2008;19:787-793.
2007-01-01	Lower urinary tract injuries associated with the out-in transobturator tape - is cystoscopy required An Argentinean multicenter experience	Altuna, et al	Int Urogynecol J (2007) 18 (Suppl 1):
2009-01-01	Clinical and Quality-of-Life Outcomes after Autologous Fascial Sling and Tension-Free Vaginal Tape: A Prospective Randomized Trial	Amaro, et al	International Braz J Urol Vol. 35 (1):60-67
1997-01-01	Classification of biomaterials and their related complications in abdominal wall hernia surgery	Amid PK	Hernia (1997) 1:15-21
2010-01-01	Complications of polypropylene mesh in prolapse surgery	Ammembal, Radley	OBSTETRICS, GYNAECOLOGY AND REPRODUCTIVE MEDICINE 20:12, 359-364
1998-01-01	Concise review of mechanisms of bacterial adhesion to biomaterial surfaces	An, Friedman	J Biomed Mater Res (Appl Biomater) 43: 338–348
2008-01-01	Foreign Body Reaction to Biomaterials	Anderson, et al	SEMIN. IMMUNOL. 20(2): 86-100

1985-01-01	Utilization of Adipose Tissue Biopsy in Characterizing Human Halogenated Hydrocarbon Exposure	Anderson, HA	Environmental Health Perspectives
2007-01-01	Prospective Clinical Trial Comparing Obtape and DUPS to TVT: One-Year Safety and Efficacy Results	Andonian, et al	European Urology 52 (2007) 245-252
2005-01-13	Randomized Clinical Trial Comparing Suprapubic Arch Sling (SPARC) and Tension-free Vaginal Tape (TVT): One-Year Results	Andonian, et al	European Urology 47 (2005) 537—541
2007-01-01	Complications of Sling Surgery Among Female Medicare Beneficiaries	Anger, et al	Obstet Gynecol 2007;109:707-14
2010-01-01	Tension-Free Vaginal Tape Versus Transobturator Suburethral Tape: Five-Year Follow-up Results of a Prospective, Randomised Trial	Angioli, et al	European Urology 58 (2010) 671-677
2009-01-01	Tension-free vaginal tape versus tension-free vaginal tape obturator (inside-outside) in the surgical treatment of female stress urinary incontinence	Aniuliene R	Medicina (Kaunas) 2009; 45(8)
1986-03-22	Epistemology of Surgery	Anon	The Lancet
2009-01-01	The influence of BMI, smoking, and age on vaginal erosions after synthetic mesh repair of pelvic organ prolapses. A multicenter study	Araco, et al	Acta Obstetricia et Gynecologica. 2009; 88: 772—780
2008-01-24	TVT-O vs TVT: a randomized trial in patients with different degrees of urinary stress incontinence	Araco, F. et al	Int Urogynecol J (2008) 19:917–926
2012-01-01	Complications from the Placement of a Tension-Free Suburethral Sling Using the Transobturator and Retropubic Methods for Treatment of Female Urinary Incontinence	Arrabal-Polo, et al	Urologia Internationalis
2003-01-01	Randomized trial of porcine dermal sling (Pelvicol implant) vs. Tension-free Vaginal Tape (TVT) in the Surgical treatment of stress incontinence: a questionnaire-based study	Arunkalaivanan, Barrington	Int Urogynecol J (2003) 14: 17—23

	SINGLE-INCISION MIDURETHRAL TAPE (OPHIRA) VS TRANSOBTURATOR TAPE (OBTRYX): PROSPECTIVE COMPARATIVE STUDY- 2 YEAR FOLLOWUP	Arunkalaivanan, et al	Abstract 245
2009-01-01	Efficacy and safety of transobturator tape (Obtryx) in women with stress urinary incontinence and intrinsic sphincter deficiency	Arunkalaivanan, et al	Presentation 778
2008-00-00	Haemorrhage and nerve damage as complications of TTVT-O procedure: case report and literature review	Atassi, et al	Arch Gynecol Obstet, 277(2), 161-164
2013-01-01	Seven years of objective and subjective outcomes of transobturator (TTV-T-O) vaginal tape: Why do tapes fail?	Athanasiou, et al	Int Urogynecol J
2009-01-01	MIXED URODYNAMIC INCONTINENCE: TTV or TTVT-O?	Athansiou, et al	Int Urogynecol J (2009) 20 (Suppl 2):S73-S239
2011-11-01	AUA Position Statement on the Use of Vaginal Mesh For the Repair of Pelvic Organ Prolapse	AUA	American Urological Association
2012-04-01	ADULT URODYNAMICS: AUA/SU FU GUIDELINE	AUA	American Urological Association Education and Research, Inc.
2009-01-01	Guideline for the Surgical Management of Female Stress Urinary Incontinence 2009 Update	AUA	
2011-11-01	AUA Position Statement on the Use of Vaginal Mesh for the Surgical Treatment of Stress Urinary Incontinence	AUA	
2013-01-01	Guidelines for Privileging and Credentialing Physicians for Sacrocolpopexy for Pelvic Organ Prolapse	AUGS	Female Pelvic Medicine & Reconstructive Surgery, 19, 2
2011-07-01	AUGS Response FDA Safety Communications	AUGS	American Urogynecologic Society
	Position Statement on Restriction of Surgical Options for Pelvic Floor Disorders	AUGS	American Urogynecologic Society
2011-09-09	AUGS statement September 8-9, 2011	AUGS	AUGS

2012-01-01	Guidelines for Providing Privileges and Credentials to Physicians for Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse	AUGS	Female Pelvic Medicine & Reconstructive Surgery Volume 18, Number 4
2014-01-01	Committee Opinion: Evaluation of Uncomplicated Stress Urinary Incontinence in Women Before Surgical Treatment	AUGS and ACOG	Female Pelvic Medicine & Reconstructive Surgery 20; 5: 248 - 251
	Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence	AUGS, SUFU	
2014-01-03	Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence	AUGS-SUFU	
2009-01-01	Do novo stress incontinence and pelvic muscle symptoms after transvaginal mesh repair	Aungst, et al	Am J Obstet Gynecol 2009;201:73.e1-7
2006-01-01	Vaginal erosion, sinus formation, and ischiorectal abscess following transobturator tape: ObTape implantation	Babalola, et al	Int Urogynecol J (2006) 17: 418—421
2004-00-00	Cystocele repair by vaginal approach with a tension-free transversal polypropylene mesh	Bader, et al	Gynécologie Obstétrique & Fertilité 32 (2004) 280--284
	Do we need meshes in pelvic floor reconstruction?	Baessler, K	World J Urol. 2012 Aug;30(4):479-86.
2005-10-01	Severe Mesh Complications Following Intravaginal Slingplasty	Baessler, et al	Obstet Gynecol 2005;106:713–6)
2006-01-01	Mesh augmentation during pelvic-floor reconstructive surgery: risks and benefits	Baessler, Maher	Curr Opin Obstet Gynecol 18:560–566
2006-01-01	Principles of Polymer Science, 2nd Edition	Bahadur, Sastry	
2009-01-01	Review of synthetic mesh-related complications in pelvic floor reconstructive surgery	Bako, Dhar	Int Urogynecol J (2009) 20:103-111
	LONG-TERM 6 YEAR PATIENT SATISFACTION AND QUALITY OF LIFE OUTCOMES AFTER AN ADVANTAGE SLINGS FOR STRESS URINARY INCONTINENCE	Balachandran, Duckett	Abstract
2008-08-01	Prospective evaluation of the safety and efficacy of the Apogee system for treatment of vault prolapse	Balakrishnan, et al	Journal of Obstetrics and Gynaecology; 28(6): 618–620

	PROSPECTIVE MULTICENTRE OBSERVATIONAL TRIAL OF COMPOSITE POLYGLACTIN/POLYPROPYLENE MESH (VYPRO* MESH) FOR RECONSTRUCTION OF RECURRENT ANTERIOR VAGINAL WALL PROLAPSE	Balmforth, Cardozo	Poster
2011-01-01	Comparison of transobturator tape (TOT) vs Burch method in treatment of stress urinary incontinence	Bandarian, et al	Journal of Obstetrics and Gynaecology, August 2011;31:518-520
2006-01-01	Abscess formation following trans-obturator tape procedures	Banks, et al	Int Urogynecol J (2006) 17 (Suppl.. 2):
2005-12-01	Contemporary views on female pelvic anatomy	Barber M	Cleveland Clinic Journal of Medicine VOLUME 72 SUPPLEMENT 4
2013-01-01	Surgical Techniques for Removing Problematic Mesh	Barber M	CLINICAL OBSTETRICS AND GYNECOLOGY Volume 56, Number 2, 289–302
2006-01-01	Perioperative complications and adverse events of the MONARC transobturator tape, compared with the tension-free vaginal tape	Barber, et al	American Journal of Obstetrics and Gynecology (2006) 195, 1820–5
2012-01-01	Single-Incision Mini-Sling Compared With Tension-Free Vaginal Tape for the Treatment of Stress Urinary Incontinence: A Randomized Controlled Trial	Barber, et al	Obstet Gynecol 2012;119:328–37)
2008-00-00	Risk factors associated with failure 1 year after retropubic or transobturator midurethral slings	Barber, et al	Am J Obstet Gynecol 199, 666 e1-7
2008-03-00	Transobturator Tape Compared With Tension-Free Vaginal Tape for the Treatment of Stress Urinary Incontinence: A Randomized Controlled Trial	Barber, et al	Obstet Cynecol 2008;111:611--21
2000-01-01	Bilateral uterosacral ligament vaginal vault suspension with site-specific endopelvic fascia defect repair for treatment of pelvic organ prolapse	Barber, et al	Am J Obstet Gynecol 2000;183:1402-11

2009-01-01	Defining Success After Surgery for Pelvic Organ Prolapse	Barber, et al	Obstet Gynecol 2009;114:600–9
	The fate of synthetic mid-urethral slings in 2013: A turning point.	Barboglio PG, and Gormley EA.	Arab Journal of Urology. 2013; 11:117-126.
1997-01-01	Intraligamentous Nerves as a Potential Source of Pain After Sacrospinous Ligament Fixation of the Vaginal Apex	Barksdale, et al	Int Urogynecol J 8:121-125
2015-02-28	The impact of boundary conditions of surface curvature of polypropylene mesh in response to uniaxial loading	Barone, et al	Journal of Biomechanics
2008-01-01	A multi-centre, randomised clinical control trial comparing the retropubic (RP) approach versus the transobturator approach (TO) for tension-free, suburethral sling treatment of urodynamic stress incontinence: the TORP study	Barry, et al	Int Urogynecol J (2008) 19:171–178
2014-01-01	Management of Mesh Complications after SUI and POP Repair: Review and Analysis of the Current Literature	Barski and Deng	BioMed Research International
	Systematic review and classification of complications after anterior, posterior, apical, and total vaginal mesh implantation for prolapse repair.	Barski D, Otto T, Gerullis H.	Surg Technol Int. 2014;24:217-24.
	Secondary surgery after vaginal prolapse repair with mesh is more common for stress incontinence and voiding dysfunction than for mesh problems or prolapse recurrence.	Bartley JM, et al.	Int Urol Nephrol. 2015;47:609-615.
2012-07-21	Transvaginal Profil mesh surgery due to advanced pelvic organ prolapse does not impair female sexual function:a prospective study	Bartuzzi, et al	European Journal of Obstetrics & Gynecology and Reproductive Biology 165 (2012) 295–298
2013-01-01	Three-year results from a randomised trial of a retropubic mid-urethral sling versus the Miniarc single incision sling for stress urinary incontinence	Basu, Duckett	Int Urogynecol J

2010-01-01	A randomised trial of a retropubic tension-free vaginal tape versus a mini-sling for stress incontinence	Basu, Duckett,	BJOG 2010;117:730—735
2001-00-00	Pain and Functional Impairment 1 Year After Inguinal Herniorrhaphy: A Nationwide Questionnaire Study	Bay-Nielsen, et al	ANNALS OF SURGERY Vol. 233, No. 1, 1-7
2007	Polypropylene midurethral tapes do not have similar biologic and biomechanical performance in the rat.	Bazi TM et al.	Eur Urol 51:1364-1375.
	Principles of Biomedical Ethics	Beauchamp, Childress	
2011-08-31	Literature Review of pelvic Organ Prolapse (POP) Repair Transvaginal Mesh	Becker & Associates Consulting, Inc	
2003-01-01	Scope and Impact of Financial Conflicts of Interest in Biomedical Research: A Systematic Review	Bekelman, et al	JAMA. 2003;289:454-465
2011-01-08	The design of an industry-sponsored randomized controlled trial to compare synthetic mesh versus biologic mesh for inguinal hernia repair	Bellows, et al	Hernia (2011) 15:325—332
2015-04-01	Considering ultrasound first for imaging the female pelvis	Benacerraf, et al	American Journal of Obstetrics & Gynecology
2012-07-03	Pelvic organ prolapse transvaginal repair by the Prolift system: Evaluation of efficacy and complications after a 4.5 years follow up	Benbouzid, et al	International Journal of Urology (2012) 19, 1010–1016
1994-00-00	Prostheses and Abdominal Wall Hernias	Bendavid R	R.G. Landes Company
1998-12-01	Complications of Groin Hernia Surgery	Bendavid R	GROIN HERNIA SURGERY VOLUME 78 NUMBER 6
2014-07-01	Mesh-Related SIN Syndrome. A Surreptitious Irreversible Neuralgia and Its Morphologic Background in the Etiology of Post-Herniorrhaphy Pain	Bendavid, et al	International Journal of Clinical Medicine, 2014, 5, 799-810
	A mechanism of mesh-related post-herniorrhaphy neuralgia	Bendavid, et al	Hernia. 2015 Nov 23. [Epub ahead of print]
1992-11-01	ANCHOR FIXATION AND OTHER MODIFICATIONS OF ENDOSCOPIC BLADDER NECK SUSPENSION	Benderev T	Urology, Vol. 40, 5:409-418

2006-01-24	Traitement du prolapsus génital avec mise en place d'une prothèse de polypropylène par voie vaginale	Benhaim, et al	J Gynecol Obstet Biol Reprod 2006 ; 35 : 219-226
2005-01-20	Pudendal neuralgia, a severe pain syndrome	Benson, Griffis	American Journal of Obstetrics and Gynecology (2005) 192, 1663-8
2011	Essentials of Pain Medicine.	Benzon H, Raja S, Liu S, Fishman S, Cohen S.	Philadelphia, PA: Elsevier Saunders.
1995-01-01	Three surgical procedures for genuine stress incontinence: Five-year follow-up of a prospective randomized study	Bergman, A; Elia, G	Am J Obstet Gynecol
2005-01-01	The Pains of Endometriosis	Berkley, et al	Science 308, 1587
2004-11-01	Conceptual advances in the surgical management of genital prolapse	Berrocal, et al	J Gynecol Obstet Biol Reprod 2004; 33:577-587
	Rising awareness of the complications of synthetic slings	Bhargava,Chapple	
2001-01-01	Trocars injuries in laparoscopic surgery	Bhoyrul, et al	J Am Coll Surg 2001;192:677–683
2011-01-01	RANDOMISED TRIAL OF TVT-O AND TVT-S FOR THE TREATMENT OF STRESS URINARY INCONTINENCE	Bianchi, et al	Int Urogynecol J (2011) 22 (Suppl 1):S1–S195
2000-01-01	Sling techniques in the treatment of genuine stress incontinence	Bidmead, Cardozo	BJOG 2000, 107(2), pp. 147-156
2010-01-01	The DSM Diagnostic Criteria for Dyspareunia	Binak V	Arch Sex Behav (2010) 39:292–303
2007-00-00	Demandes and properties of alloplastic implants for the treatment of stress urinary incontinence	Binneboesel, et al	Expert Review of Medical Devices
2011-01-12	Biocompatibility of prosthetic meshes in abdominal surgery	Binneboesel, et al	Semin Immunopathol (2011) 33:235–243
2002-01-01	The role of synthetic and biological prostheses in reconstructive pelvic floor surgery	Birch, Fynes	Curr Opin Obstet Gynecol 14:527-535
2013-04-19	Mesh cancer: long-term mesh infection leading to squamous-cell carcinoma of the abdominal wall	Birolini, et al	Hernia
2004-01-01	Urethral reconstruction after erosion of slings in women	Blaivas and Sandhu	Current Opinion in Urology 2004, 14:335–338
	NOT THE CORRECT CHOICE	Blaivas JG	

2011-01-01	Pubovaginal Fascial Sling for the Treatment of all Types of Stress Urinary Incontinence: Surgical Technique and Long-term Outcome	Blaivas, Chaikin	Urol Clin N Am
2013-10-01	Salvage Surgery after Failed Treatment of Synthetic Mesh Sling Complications	Blaivas, et al	J Urol Vol. 190, 1281-1286
2014-01-01	Management of Urinary Fistulas Due to Midurethral Sling Surgery	Blaivas, et al	J Urol 2014
2015-08-15	Safety considerations for synthetic sling surgery	Blaivas, et al	Nat. Rev. Urol. advance online publication 18 August 2015; doi:10.1038/nrurol.2015.183
2008-01-01	Post-Traumatic Female Urethral Reconstruction	Blaivas, Purohit	Current Urology Reports 2008, 9: 397 – 404
2012-11-01	Management of Urethral Stricture in Women	Blaivas, et al	J Urol 188:1779-1792 (2012)
2009-02-10	Complications from vaginally placed mesh in pelvic reconstructive surgery	Blandon, et al	Int Urogynecol J (2009) 20:523–531
2013-10-01	AUA Position Statement On The Use Of Vaginal Mesh For The Surgical Treatment Of Stress Urinary Incontinence	Board of Directors, AUA (Revised)	AUA website
	Short term complications of the tension free vaginal tape operation for stress urinary incontinence in women	Bodelsson, et al	
2009-01-01	Pelvic nerve injury following gynecologic surgery: a prospective cohort study	Bohrer, et al	Am J Obstet Gynecol 2009;201:531.e1-7
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2012-01-01	A perfect storm	Brubaker, Shull	Int Urogynecol J (2012) 23:3-4
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1968-01-01	Cooper's ligament urethrovesical suspension for stress incontinence	Burch, JC	Am J Obstet Gynecol
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1999-01-01	Surgical Implants and Other Foreign Bodies	IARC Working Group on the Evaluation of Carcinogenic Risks to Humans	
2013-07-01	ICS Fact Sheets - A background to Urinary and Faecal Incontinence	ICS	
	The Use of Mesh in Gynecologic Surgery	Iglesia, et al	
2010-08-01	Vaginal Mesh For Prolapse: A Randomized Controlled Trial	Iglesia, et al	Obstet Gynecol 2010;116:293–303
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	In vivo oxidative degradation of polypropylene pelvic mesh	Imel, A, et al.	Biomaterials. 2015 Dec; 73:131-41.
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2007-09-01	Vaginal mesh for incontinence and/or prolapse:caution required	Isom-Batz, Zimmern	Expert Review of Medical Devices. 4.5 (Sept. 2007): p 675
2013-01-01	Position Statement on MUS; Position Statement on Mid-Urethral Slings for Stress Urinary Incontinence	IUGA	IUGA website

2011-01-01	Stress Urinary Incontinence A Guide for Women	IUGA	
2013-00-00	A decision-analytic Markov model to compare the cost—utility of anterior repair augmented with synthetic mesh compared with non-mesh repair in women with surgically treated prolapse	Jacklin, Duckett	BJOG 2013;120:217-223.
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	PROSPECTIVE CLINICAL ASSESSMENT OF THE TRANS VAGINAL MESH (TVM) TECHNIQUE FOR TREATMENT OF PELVIC ORGAN PROLAPSE —ONE YEAR RESULTS OF 175 PATIENTS	Jacquetin, et al	Poster
2010-01-01	Total transvaginal mesh (TVM) technique for treatment of pelvic organ prolapse: a 3-year prospective follow-up study	Jacquetin, et al	
2004-08-25	A meta-analysis of the Intra-Operative Safety and Effectiveness of the Transobturator Hammock Seen in Results of Two Prospective Studies in 9 Countries with 204 Patients	Jacquetin, et al	ICS/IUGA Annual Meeting
2015-04-04	Intravesical midurethral sling mesh erosion secondary to transvaginal mesh reconstructive surgery	Jaili, et al	Gynecology and Minimally Invasive Therapy
2011-00-00	Effectiveness of midurethral slings in mixed urinary incontinence: a systematic review and meta-analysis	Jain, et al	Int Urogynecol J (2011) 22:923-932
2007-01-01	SINGLE-BLIND RANDOMIZED CLINICAL TRIAL COMPARING EFFICACY AND SAFETY OF TVT (TENSION FREE VAGINAL TAPE) VS TVT-O (TENSION FREE VAGINAL TAPE OBTURATOR SYSTEM) IN TREATMENT OF STRESS URINARY INCONTINENCE-POLTO PRELIMINARY REPORT	Jakimiuk, et al	Int Urogynecol J (2007) 18 (Suppl 1):S107–S244
2008-01-01	Biologic and Synthetic Graft Use in Pelvic Surgery: A Review	Jakus, et al	Volume 63, Number 4 OBSTETRICAL AND GYNECOLOGICAL SURVEY
2015-08-20	The impact of prolapse mesh on vaginal smooth muscle structure and function	Jallah, et al.	BJOG

2009-01-01	RANDOMISED TRIAL OF TVT-O AND TVT-S FOR THE TREATMENT OF STRESS URINARY INCONTINENCE PRELIMINARY STUDY	Jarmy-Di Bella, et al	Int Urogynecol J (2009) 20 (Suppl 2):S73–S239
2014-01-01	High risk of complications with a single incision pelvic floor repair kit results of a retrospective case series	Jeffery, Brouard	Int Urogynecol J (2014) 25:109–116
	Stress urinary incontinence in women: Choosing a type of midurethral sling	Jelovsek, et al	
	Randomised trial of laparoscopic Burch colposuspension versus tension-free vaginal tape: long-term follow up	Jelovsek, et al	
2007-01-01	Pelvic organ prolapse	Jelovsek, et al	Lancet Vol 369
	The clinical picture of neuropathic pain	Jensen, et al	
2014-00-00	Evaluation of three purely polypropylene meshes of different pore sizes in an onlay position in a New Zealand white rabbit model	Jerabek, et al	Hernia (2014) 18:855–864
	Impact of incontinence surgery on sexual function: a systematic review and meta-analysis.	Jha S, et al.	J Sex Med. 2012 Jan;9(1):34-43.
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2008-06-10	Efficacy and safety of using mesh or grafts in surgery for anterior and/or posterior vaginal wall prolapse: systematic review and meta-analysis	Jia, et al	BJOG 2008;115:1350–1361
2014-11-20	A Multicenter, Prospective Trial to Evaluate Mesh-Augmented Sacrospinous Hysteropexy for Uterovaginal Prolapse	Jirschele, et al	International Urogynecology Journal 10.1007/s00192-014-2564-x
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2009-07-01	Tensile properties of commonly used prolapse meshes	Jones, et al	Int Urogynecol J Pelvic Floor Dysfunct
2010-00-00	Letter to the editor: Risk of Tape-Related Complications After TVT Is At Least 4%	Jones, et al	Neurourology and Urodynamics 29:40-41 (2010)
1986-01-01	Degradation of polypropylene in the human eye: A semi-study	Jongebloed, Worst	Documenta Ophthalmologica 64:143-152
	Transobturatoric tape procedure for female stress urinary incontinence	Joutsiniemi, et al	
2007-01-16	Efficacy Analysis of Trans-obturator Tension-free Vaginal Tape (TVT-O) Plus Modified Ingelman-Sundberg Procedure versus TVT-O Alone in the Treatment of Mixed Urinary Incontinence: A Randomized Study	Juang, et al	European Urology 51 (2007) 1671-1679
2009-01-01	Long Term Experience in 72 Patients with the Advantage Sling System	Julia, Cholhan	Boston Scientific Marketing
1996-01-01	The efficacy of Marlex mesh in the repair of severe, recurrent vaginal prolapse of the anterior midvaginal wall	Julian T	Am J Obstet Gynecol 1996; 175:1472-5
2002-00-00	Influence of Mesh Materials on Collagen Deposition in a Rat Model	Junge, et al	J Invest Surg 2002; 15: 319-328
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	Which sling for which patient?	Karram M	
2015-01-01	Managing Mesh and Other Complications After Surgeries for Urinary Incontinence and Pelvic Organ Prolapse; Chapter 30	Karram, Gebhart	Urogynecology and Reconstructive Pelvic Surgery
2007-01-01	AN EVALUATION OF THE GYNECARE TVT SECUR* SYSTEM (TENSION-FREE SUPPORT FOR INCONTINENCE) FOR THE TREATMENTT OF STRESS URINARY INCONTINENCE	Karram, et al	Int Urogynecol J (2007) 18 (Suppl 1):S1-S24

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2013-01-01	OUTCOMES AND COMPLICATIONS OF BURCH, FASCIAL, AND MIDURETHRAL SLINGS	Kenton, et al	ICS 2013, Barcelona
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2007-01-01	Thoughts on Midurethral Synthetic Slings	Serels, Scott	Current Urology Reports
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2011-07-25	Society of Gynecologic Surgeons (SGS) Executive Committee Statement Regarding the FDA Communication	Society of Gynecologic Surgeons (SGS) Executive Committee	
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2009-02-04	Perineal approach to vascular anatomy during transobturator cystocele repair	Touboul, et al	BJOG 2009;116:708-712
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2014-01-01	Overview of transvaginal placement of reconstructive materials (surgical mesh or biografts) for treatment of pelvic organ prolapse or stress urinary incontinence	Trabuco, Gebhart	UpToDate
2011-08-30	Safety and Effectiveness of Transvaginal Surgical Mesh Used for Repair of Pelvic Organ Prolapse	Transvaginal mesh Industry Working Group, et al	
2014-01-01	Characteristics and temporal trends in patient registries: focus on the life sciences industry, 1981–2012	Travers, et al	Pharmacoepidemiology and Drug Safety
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Deposition of Aaron Kirkemo, dated Apr. 8, 2012 and exhibits
Deposition of Brigitte Hellhammer, dated Sept. 11-12, 2013 and exhibits
Deposition of Bryan Lisa, dated Dec. 12, 2011, and exhibits
Deposition of Catherine Beath, dated Mar. 27, 2012 and exhibits
Deposition of David Robinson dated Sept. 11, 2013 and exhibits
Deposition of Giselle Bonet, dated Mar. 5, 2012, and exhibits
Deposition of Laura Angelini, dated June 19, 2015
Deposition of Maggie D'Aversa, dated Feb. 28, 2012 and exhibits
Deposition of Meng Chen, Ph.D., dated Oct. 29-30, 2013, and exhibits
Deposition of Piet Hinoul, dated Apr. 6, 2012, and exhibits
Deposition of Scott Jones, dated Nov. 16, 2011 and Jan. 25, 2012, and exhibits
Deposition of Stacy Hoffman, dated March 13-15, 2012, Ex. 541
Deposition of Thomas Barbolt, dated October 10, 2012
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